

**From:** Koerber, Mike  
**To:** Woods, Clint; Lewis, Josh; Tsirigotis, Peter  
**Cc:** Davis, Alison; Sasser, Erika; Wayland, Richard; Cozzie, David  
**Subject:** Draft talking points  
**Date:** Thursday, July 26, 2018 5:03:43 AM  
**Attachments:** Suggested key points to cover with RAs july 26.docx

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Clint: Here are draft talking points to use for today's call with the RAs. Let me know what you think. My understanding is that Bill intends to kick-off the call and then hand it to OAQPS. Thanks.

Mike

## Suggested key points to cover with RAs re: ethylene oxide

- Be consistent, stay coordinated - *stress the importance of working together and not getting out ahead of one another*. We know you have a variety of challenges at the local level, and there are important differences in those situations, but we do need to have a consistent approach and act in a coordinated manner.
- NATA data
  - The NATA results we talked about last time represent long-term, chronic risks – which the numbers suggest may be serious.
  - NATA does not assess acute risks. So, we plan to look further at our information to confirm that there are no acute risk concerns.
  - Given the number of facilities in play, the many regions affected, and the diversity of source categories, a consistent national approach is necessary.
- Hybrid strategy
  - First, I believe that a regulatory approach based on our CAA section 112 authorities is the most efficient and appropriate approach to take to reduce risks associated with emissions of ethylene oxide. To this end, I've asked OAQPS to scope out a plan for taking expeditious regulatory action. While this will take time to fully implement (and achieve emission reductions), I've asked that they deliver a draft plan as soon as possible.
  - Second, I think there may also be a need to take more immediate actions for a subset of facilities where emissions may pose a higher risk. These actions should focus on gathering data that can both inform the regulatory actions, as well as any near-term emission reduction opportunities.
  - We are still working to identify these facilities and will be talking with your Air Division Directors about this shortly.
- Engagement with Regions
  - Following this call, OAQPS will share the latest NATA results with all of you. Over the next 2 weeks, we ask that your staff review and verify these data, and work with the OAQPS team to make any necessary updates or changes. This may refine our list of areas and sources for further consideration, so your assistance is critical to ensuring we have the correct starting point for our next step actions to address potential health risks. We will reconvene with your staff to confirm the data upon completion of the 2-week review.

- While we don't yet have a schedule for public release of NATA, we will work with you in advance to prepare for the NATA release.
  - OAQPS needs to work directly with your Air Division Directors (and appropriate staff) to flesh out key details of the hybrid strategy. This will include making sure that we have key information for EtO-emitting facilities, and that any more immediate actions are focused on the right facilities.
  - OAQPS is drafting a communications strategy to cover both the NATA release and the ethylene oxide work. As we get closer to making NATA public, OAR and OAQPS will reach out to coordinate with appropriate Regional Office communications staff.
- Next Steps
    - We need to move quickly to make to finalize our plans and prepare for the public release of NATA. I intend to outline what we will do to address ethylene oxide at that time.
    - As I said, we will be reaching out to your ADDs following this call on reviewing the NATA data and discussing individual EtO-emitting facilities.
    - Again, I want to say how important it is to be consistent and stay coordinated.

**From:** Rakosnik, Delaney on behalf of Wehrum, Bill  
**To:** Harlow, David; Woods, Clint; Tsirigotis, Peter; Koerber, Mike; Sasser, Erika; Lassiter, Penny; Langdon, Robin; Shine, Brenda; Caparoso, Jennifer; Smith, Darcie; Strum, Madeleine; Palma, Ted; Cozzie, David; Witt, Jon; Lavoie, Tegan; Bremer, Kristen; Vasu, Amy; Noonan, Jenny; Vandenberg, John; Thayer, Kris; Berner, Ted; Wayland, Richard; Shelow, David; Shapple, Ned; Conner, Lisa  
**Subject:** Ethylene Oxide

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TO: Wehrum, Bill; Harlow, David; Woods, Clint; Tsirigotis, Peter; Koerber, Mike; Sasser, Erika; Lassiter, Penny; Langdon, Robin; Shine, Brenda; Caparoso, Jennifer; Smith, Darcie; Strum, Madeleine; Palma, Ted; Cozzie, David; Witt, Jon; Lavoie, Tegan; Bremer, Kristen; Vasu, Amy; Noonan, Jenny; Vandenberg, John; Thayer, Kris; Berner, Ted; Wayland, Richard; Shelow, David; Shapple, Ned; Conner, Lisa

## Mahgoub, Gaida

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**From:** Koerber, Mike  
**Sent:** Wednesday, September 26, 2018 8:14 AM  
**To:** Rimer, Kelly; Smith, Darcie; Bremer, Kristen; Davis, Alison; Cortelyou-Lee, Jan  
**Cc:** Lessard, Patrick  
**Subject:** FW: Updated language on ETO and IRIS assessment  
**Attachments:** Background Materials for Mtg w Willowbrook Leadership 09 21 18 Draft w ORD version2.docx

Clint would like to provide this to OCIR for use in responding to inquiries and, perhaps, as a public document (in some form to be determined). He would like our feedback (and tweaks) by 9:00 am this morning. So, send me any comments by 8:45 am and I will forward to Clint. Please let me know if you have any questions.

Mike

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**From:** Koerber, Mike  
**Sent:** Friday, September 21, 2018 2:47 PM  
**To:** Woods, Clint <[woods.Clint@epa.gov](mailto:woods.Clint@epa.gov)>  
**Cc:** Lewis, Josh <[Lewis.Josh@epa.gov](mailto:Lewis.Josh@epa.gov)>  
**Subject:** RE: Updated language on ETO and IRIS assessment

Updated version with additional ORD input – see page 3 (Toxicity).

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**From:** Koerber, Mike  
**Sent:** Friday, September 21, 2018 12:42 PM  
**To:** Woods, Clint <[woods.Clint@epa.gov](mailto:woods.Clint@epa.gov)>  
**Cc:** Lewis, Josh <[Lewis.Josh@epa.gov](mailto:Lewis.Josh@epa.gov)>  
**Subject:** FW: Updated language on ETO and IRIS assessment

Clint: Here is the draft pager for the upcoming meeting. We folded in the piece from Lou that we received this morning. Any comments would be appreciated.

Mike

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**From:** D'Amico, Louis  
**Sent:** Friday, September 21, 2018 11:42 AM  
**To:** Rimer, Kelly <[Rimer.Kelly@epa.gov](mailto:Rimer.Kelly@epa.gov)>; Koerber, Mike <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)>  
**Cc:** Orme-Zavaleta, Jennifer <[Orme-Zavaleta.Jennifer@epa.gov](mailto:Orme-Zavaleta.Jennifer@epa.gov)>  
**Subject:** Updated language on ETO and IRIS assessment

Hi Kelly,

Attached is some language on EtO that ORD has developed to talk about the IRIS assessment. Let me know if you have any questions. If there's any feedback or other information you need, feel free to reach out.

Best,  
Lou

Louis D'Amico, Ph.D.  
Senior Science Advisor

Office of Research and Development  
U.S. Environmental Protection Agency  
Mail Code 8101R | 1200 Pennsylvania Ave, NW | Washington, DC 20460

Office: 202-564-4605 | Mobile: 703-859-1719 | email: [damico.louis@epa.gov](mailto:damico.louis@epa.gov)

## Mahgoub, Gaida

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**From:** Koerber, Mike  
**Sent:** Thursday, September 27, 2018 1:46 PM  
**To:** Bremer, Kristen; Davis, Alison  
**Cc:** Rimer, Kelly  
**Subject:** FW: R5  
**Attachments:** Sterigenics\_8.22 web copy.pdf

Please take a look and let me know what you think.

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**From:** Woods, Clint  
**Sent:** Thursday, September 27, 2018 1:40 PM  
**To:** Koerber, Mike <Koerber.Mike@epa.gov>  
**Subject:** R5

Mike,

Attached is pdf of R5 website, which we had asked to reformat for national consistency. Can you take a look for content red flags or formatting changes we would suggest? Trying to get on read on whether this is a short term ask (post the pdf) or something where we could day a couple days to tighten up the page to match previous R6-type sites.

Thanks!

Clint Woods  
Deputy Assistant Administrator  
Office of Air and Radiation, U.S. EPA  
202.564.6562

## Mahgoub, Gaida

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**From:** Koerber, Mike  
**Sent:** Thursday, September 27, 2018 5:13 PM  
**To:** Bremer, Kristen; Davis, Alison; Woods, Clint  
**Cc:** Rimer, Kelly  
**Subject:** RE: R5

Thanks, Kristen. In addition, the format of the Region 6 page (<https://www.epa.gov/la/laplace-st-john-baptist-parish-louisiana>) would provide a good model for this Region 5 page.

Mike

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**From:** Bremer, Kristen  
**Sent:** Thursday, September 27, 2018 2:17 PM  
**To:** Koerber, Mike <Koerber.Mike@epa.gov>; Davis, Alison <Davis.Alison@epa.gov>  
**Cc:** Rimer, Kelly <Rimer.Kelly@epa.gov>  
**Subject:** RE: R5

# Ex. 5 Deliberative Process (DP)

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Kristen Bremer  
Policy Analysis & Communications  
U.S. EPA, Office of Air Quality Planning & Standards  
Email: [bremer.kristen@epa.gov](mailto:bremer.kristen@epa.gov)  
Phone: 919.541.9424  
Cell: 919.321.7652

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**From:** Koerber, Mike  
**Sent:** Thursday, September 27, 2018 1:46 PM  
**To:** Bremer, Kristen <[Bremer.Kristen@epa.gov](mailto:Bremer.Kristen@epa.gov)>; Davis, Alison <[Davis.Alison@epa.gov](mailto:Davis.Alison@epa.gov)>  
**Cc:** Rimer, Kelly <[Rimer.Kelly@epa.gov](mailto:Rimer.Kelly@epa.gov)>  
**Subject:** FW: R5

Please take a look and let me know what you think.

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**From:** Woods, Clint  
**Sent:** Thursday, September 27, 2018 1:40 PM  
**To:** Koerber, Mike <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)>  
**Subject:** R5

Mike,

Attached is pdf of R5 website, which we had asked to reformat for national consistency. Can you take a look for content red flags or formatting changes we would suggest? Trying to get on read on whether this is a short term ask (post the pdf) or something where we could day a couple days to tighten up the page to match previous R6-type sites.

Thanks!

Clint Woods  
Deputy Assistant Administrator  
Office of Air and Radiation, U.S. EPA  
202.564.6562

## Mahgoub, Gaida

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**From:** Lessard, Patrick  
**Sent:** Wednesday, October 17, 2018 4:57 PM  
**To:** OAQPS SMT1; OAQPS SMT2  
**Cc:** McKinney, Voronina; Koerber, Mike  
**Subject:** Agenda: Bill Wehrum Visit to EPA RTP

Hello,






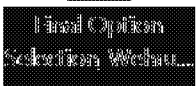


Here are the agenda and materials for tomorrow. All meetings will be in Room C401A.



Let me or Mike know if you have any questions.

### Assistant Administrator Bill Wehrum Visit to EPA RTP

#### Thursday (10/18)

All meetings to be held in EPA RTP Room C401A

7:57 am	Bill W, Mandy G and David H arrive at RDU (AA, Flight No. 4667)
8:30 to 9:15 am	ACE Update Meeting   ACE Schedule Meeting NW 1001...
9:30 to 10:15 am	SO2 Primary NAAQS Discussion   SO2 SO2 Addition Information...
10:30 to 11:15 am	Option Selection for Reclassification of Major Sources as Area Sources (MM2A) Under Section 112 of the Clean Air Act   Final Option Selection Wehrum...
11:30 to 12:15 pm	O3 NAAQS Review - Draft IRP for CASAC/Public Release   O3 NAAQS Data...
12:15 to 1:15 pm	Working Lunch with HEID/ATAG to discuss Ethylene Oxide Update (Room C401A)
1:30 pm	Bill W, Mandy G, Alex D and Peter T depart for airport
1:30 to 2:30 pm	NSR Update Meeting (No materials)
2:45 to 3:45 pm	NUCOR Letter Response Update (Materials pending)
3:04 pm	Bill W, Mandy G, Alex D and Peter T depart at RDU (AA Flight No. 5213)

4:00 to 5:00 pm	Discussion About Upcoming Title V Petitions  
5:15 pm	David H depart for airport
6:47 pm	David H depart at RDU (AA Flight No. 5183)

Thank you,

Patrick Lessard  
U.S. Environmental Protection Agency  
Office of Air Quality Planning and Standards  
(919) 541-5383

**From:** [Wehrum, Bill](#)  
**To:** [Tsirigotis, Peter](#); [Koerber, Mike](#)  
**Cc:** [Gunasekara, Mandy](#); [Woods, Clint](#)  
**Subject:** FW: ATSDR Sterigenics EtO Consult Letter-final.pdf  
**Date:** Thursday, July 26, 2018 1:59:49 PM  
**Attachments:** [ATSDR Sterigenics EtO Consult Letter-final.pdf](#)  
[ATT00001.htm](#)

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Bill Wehrum  
Assistant Administrator  
Office of Air and Radiation  
U.S. Environmental Protection Agency  
(202) 564-7404

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**From:** Stepp, Cathy  
**Sent:** Thursday, July 26, 2018 1:21 PM  
**To:** Wehrum, Bill <[Wehrum.Bill@epa.gov](mailto:Wehrum.Bill@epa.gov)>  
**Subject:** ATSDR Sterigenics EtO Consult Letter-final.pdf



**DEPARTMENT OF HEALTH & HUMAN SERVICES**  
Agency for Toxic Substances and Disease Registry,  
Region 5

Public Health Service  
77 W. Jackson Blvd., Room 413  
Chicago, IL 60604

July 26, 2018

Ed Nam  
Director, Air and Radiation Division  
United States Environmental Protection Agency, Region 5  
77 W. Jackson Blvd., MS A-18J  
Chicago, IL 60604

Dear Mr. Nam:

Since February 2018, ATSDR has met with U.S. EPA Region 5 Air and Radiation Division (ARD) staff regarding a change in the cancer risk basis for ethylene oxide (EtO) in the EPA Integrated Risk Information System (IRIS) and how that change affects general population risks estimated from EtO-emitting facilities in the draft 2014 National Air Toxics Assessment (NATA) update<sup>1</sup>. In December 2016, IRIS changed EtO's adult-based inhalation unit risk from 0.0001 per microgram per cubic meter ( $\mu\text{g}/\text{m}^3$ ) to 0.003 per  $\mu\text{g}/\text{m}^3$ , a 30-fold increase in cancer potency. It also changed EtO's cancer weight-of-evidence descriptor from "probably carcinogenic to humans" to "carcinogenic to humans". These changes could result in many census tracts having estimated cancer risks that are greater than 1 in 10,000 from EtO exposure identified through the draft NATA modeling of air emissions across the United States.

Specifically, ARD decided to evaluate the implications of this change at two sites, Sterigenics International, Inc. (referred to in the letter as "*Sterigenics*") in Willowbrook, IL and the Elé Corporation in McCook, IL. This letter addresses EtO emissions from the Sterigenics facility. In June 2018, after the monitoring results were received and reviewed, ARD requested that ATSDR review air measurements of EtO and modeling results of EtO emissions from Sterigenics and specifically answer the question: *If modeled and measured ethylene oxide concentrations represent long term conditions, would they pose a public health problem for people living and working in Willowbrook?*

The air modeling data that U.S. EPA provided to ATSDR estimated potential short-term and long-term concentrations of EtO in ambient air surrounding the Sterigenics Corporation. Follow-up air monitoring data confirm the presence of elevated EtO at concentrations within a similar range to those estimated by the air modeling of Sterigenics emissions. Based on these measured and modeled concentrations and the proximity to residences and other commercial structures, cancer risks higher than 1 in 10,000 people may exist for some community members and workers exposed to airborne EtO in this community. If these measured and estimated concentrations represent chronic exposures

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<sup>1</sup> The 2014 NATA is expected to be publicly available in the fall of 2018.

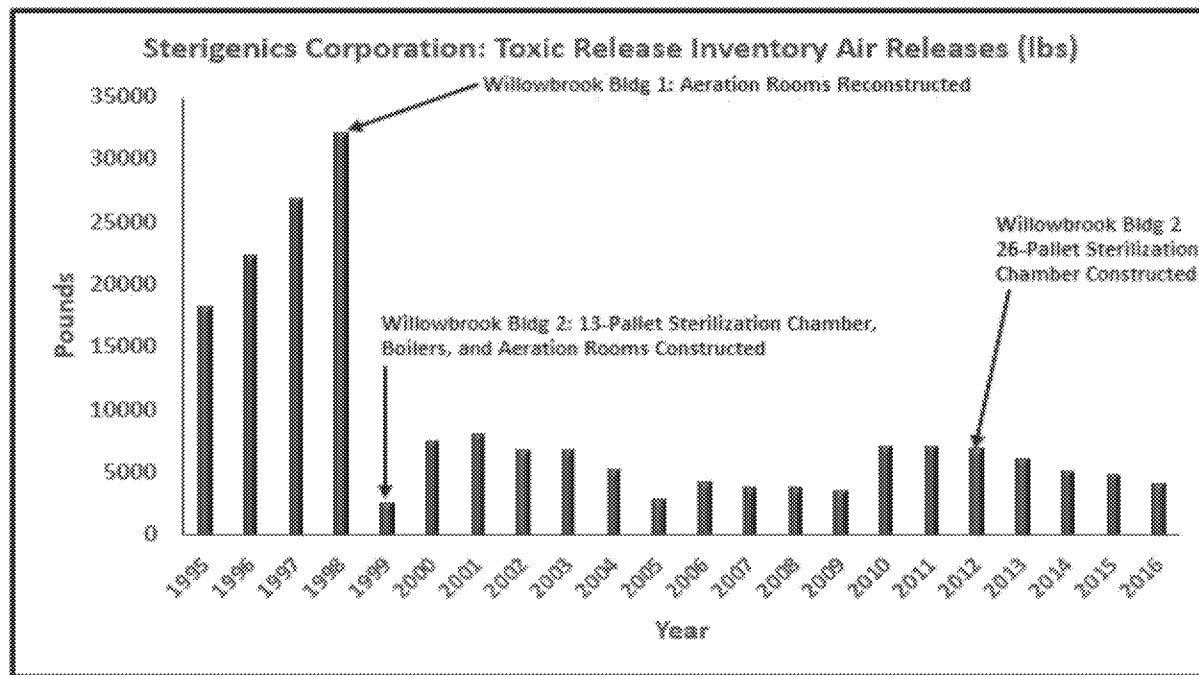
in the surrounding community (with higher exposures likely for workers of the facility), EtO emissions from the Sterigenics Corporation poses a public health hazard.

## BACKGROUND

Sterigenics provides sterilization processes using gamma, ethylene oxide, Ebeam, and X-ray sterilization and operates 46 facilities in 13 countries (Sterigenics, 2018). The facility stores ethylene oxide that is sprayed into sealed chambers to sterilize medical equipment, pharmaceuticals, and food/spice products contained on 40" x 48" pallets. The sterilization chambers are contained in two buildings. Building 1 has fifteen chambers that can hold 1 to 13 pallets, while Building 2 has four sterilization chambers that can hold 13 to 26 pallets (Illinois EPA, 2017). Building 1 chambers were constructed in 1984, while Building 2 chambers were built in 1999 and 2012. Pollution control technology includes acid water scrubbers and dry bed reactors that convert the ethylene oxide to ethylene glycol after the sterilization process (Illinois EPA, 2015). Although back vents on the units have historically been uncontrolled, Sterigenics is currently in the process of installing pollution controls to control passive releases (ATSDR, 2018).

Figure 1 illustrates the total reported emissions in pounds per year (lbs/yr) of EtO from Sterigenics.

**Figure 1. TRI Total Air Emissions Reported (in pounds), by Sterigenics Corporation for Ethylene Oxide, 1995-2016**



<sup>a</sup>Source: Toxic Release Inventory (TRI): <https://www.epa.gov/enviro/tri-overview>

<sup>b</sup>Dates for facility constructed and upgrades were identified according to Illinois EPA (2017) DRAFT/PROPOSED Clean Air Act Permit Program (CAAPP) Permit

The emissions data show a substantial reduction in total air releases after 1998. No data are available before 1995 on ambient air releases, but the available data suggests that substantially higher ambient releases prior to 1995 were likely. The Building 1 sterilization chambers were constructed in 1984, therefore EtO has been emitted over the past 34 years from the Willowbrook facility.

Willowbrook, Illinois is a small suburb of Chicago with approximately 8,500 residents (U.S. Census, 2016). The Willowbrook industrial complex where Sterigenics is located is in a densely populated metropolitan area, with 19,271 people living within 1 mile of the facility boundary. There are four schools and one daycare facility within 1 mile of the facility. According to 2016 Census estimates, Willowbrook residents are predominately white (73.3%), non-Hispanic (66.6%), educated (97.7% graduate high school, and 48.9% graduated with a bachelor's degree or higher), and middle class (median household income was over \$67,000 per year). Approximately 18.5% of the population is identified as Asian, and 6.3% as black.

**Figure 2. Aerial map of the community surrounding Sterigenics Corporation**



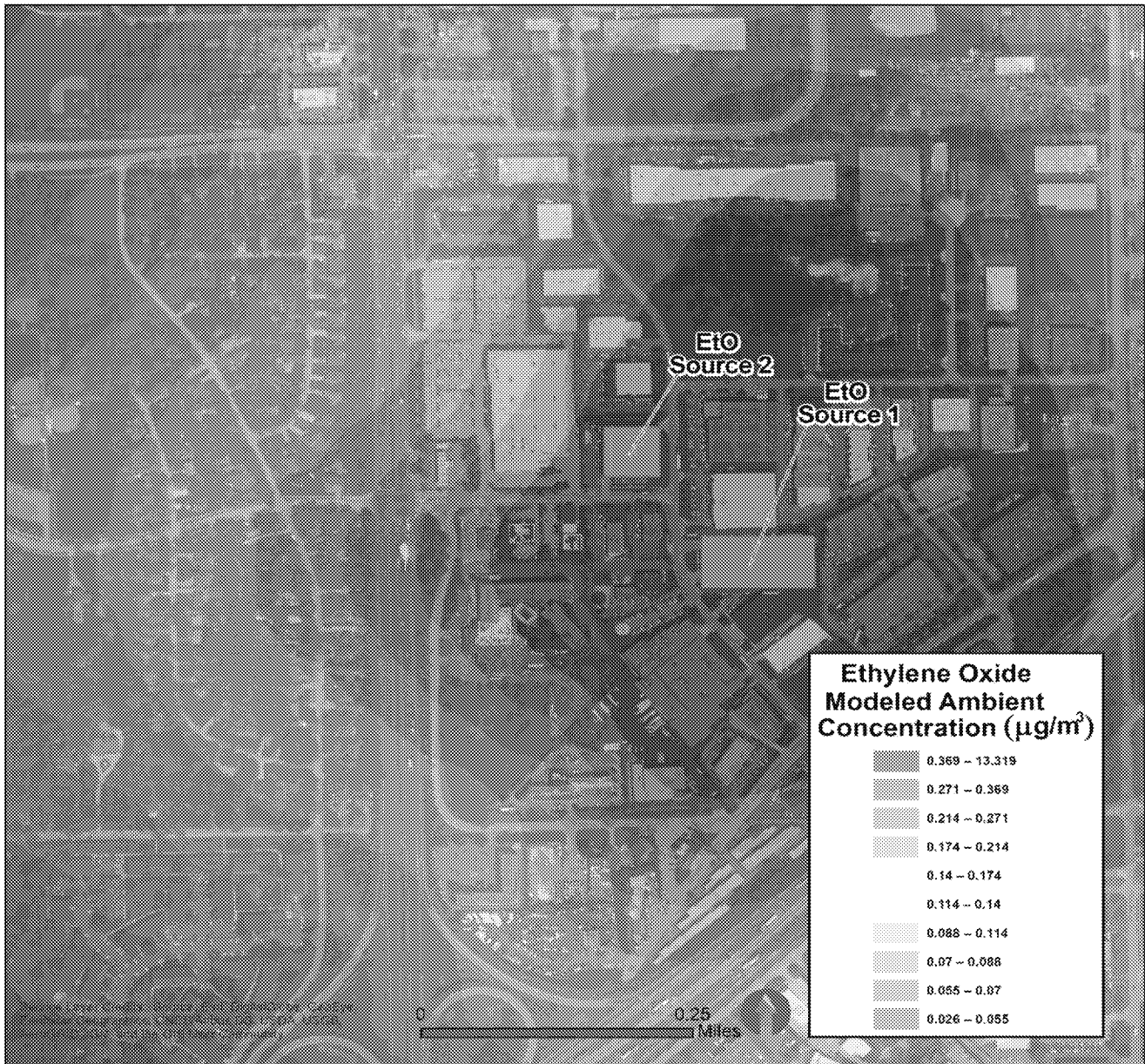
Source: Google Earth

ENVIRONMENTAL DATA

Air Modeling

U.S. EPA modeled short and long-term ambient EtO concentrations (AERMOD version 18081) to evaluate the potential impact of site emissions. These scenarios estimated a 5-year average to represent chronic exposures and maximum 1- and 8-hour averages to represent acute exposures at 882 community receptor points. An overlay of the modeling output is displayed in Figure 3, below. The statistical distributions of the modeled air concentrations are presented in Table 1.

Figure 3. AERMOD modeling output: 5-year average exposure estimates



Source: U.S. EPA Air and Radiation Division, Region 5

Note: Source 1 is Sterigenics Willowbrook Building 1, and Source 2 is Sterigenics Willowbrook Building 2

**Table 1. Statistical distribution of EtO modeling\***

Statistics	Modeled 1-hour ( $\mu\text{g}/\text{m}^3$ )	Modeled 8-hour ( $\mu\text{g}/\text{m}^3$ )	Modeled 5-year ( $\mu\text{g}/\text{m}^3$ )
Minimum	2.17	1.02	0.03
25th Percentile	4.62	2.26	0.09
50th Percentile	9.72	4.07	0.17
75th Percentile	18.88	7.29	0.31
90th Percentile	33.90	12.62	0.57
95th Percentile	45.22	18.83	0.91
99th Percentile	134.73	61.39	2.97
Maximum	249.77	123.89	13.32
Mean	15.75	6.72	0.32
Geometric Mean	10.13	4.41	0.18

\*N= 882 modeled receptors

### **Air Measurements**

U.S. EPA collected 39 validated samples May 16<sup>th</sup> and May 17<sup>th</sup>, 2018. These samples were collected using SUMMA® canisters, and analyzed using U.S. EPA Compendium Method TO-15, Compendium of Methods for the Determination of Toxic Organic Compounds in Ambient Air. A SUMMA® canister is an airtight, stainless-steel container with an inner surface that has been electro-polished and chemically deactivated. The laboratory is required to clean each canister and evacuate it to a high vacuum prior to shipping it to the sampling location. A canister can hold the vacuum for up to 30 days. The air being sampled is “drawn” into the canister by the high vacuum, thus eliminating the need for a pump. While opening the inlet orifice fills the canister in less than a minute, yielding an instantaneous “grab” sample, regulators can be added to the inlet orifice to draw the air into the canister over a designated period, ranging from 1 to 24-hours.

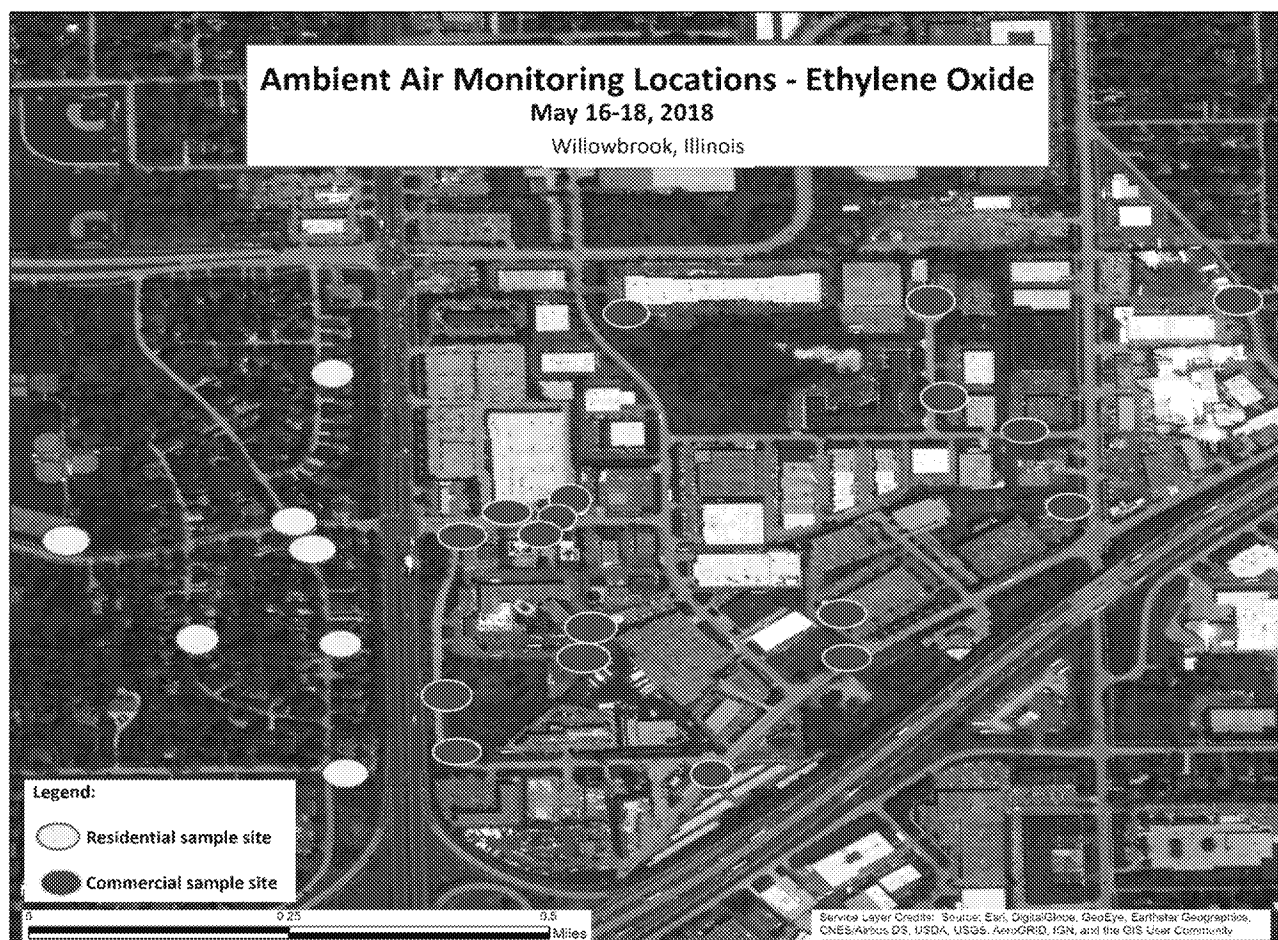
Of the 39 samples collected at 26 discrete locations (Figure 4), 18 were 12-hour samples, and 21 were grab samples (Table 2). Three of the 12-hour samples were collocated duplicates, and three of the grab samples were collocated duplicates. Grab samples generally had lower EtO concentrations than 12-hour averaged samples (U.S. EPA, 2018). However, all grab samples were collected between 10:20 am and 3:05 pm. ARD staff noted that higher EtO concentrations were measured overnight than during the day, and 12-hour samples were collected overnight in some locations. Since Sterigenics is a 24-hour operation, this may be due to calm meteorological conditions overnight with a higher potential for inversions. Given the elevated detections over a limited duration, additional long-term sampling is warranted to better characterize residential exposure to EtO.

**Table 2. Statistical distribution of residential and commercial EtO air sampling\***

Statistics	Grab samples ( $\mu\text{g}/\text{m}^3$ )	12-hour samples ( $\mu\text{g}/\text{m}^3$ )
Min	0.16	0.34
25th Percentile	0.24	0.69
50th Percentile	0.45	1.56
75th Percentile	1.34	4.39
90th Percentile	2.28	8.26
95th Percentile	4.27	8.44
99th Percentile	4.33	8.96
Max	4.34	9.09
Mean	1.07	3.02
Geo Mean	0.62	1.74

*\*N=21 grab samples, 18 12-hour samples*

**Figure 4. Ambient air samples near the Sterigenics facility, Willowbrook, IL**



*Source: U.S. EPA, Region 5*

Figure 4, shows the location of discrete samples collected in the community. Given limited measured data presented in Table 2, ATSDR used the maximum 12-hour residential sample concentration and the maximum 12-hour commercial sample concentration to represent chronic upper bound residential ( $2.1 \mu\text{g}/\text{m}^3$ ) and occupational ( $9.1 \mu\text{g}/\text{m}^3$ ) exposures in the community. These concentrations represent maximums identified during a very temporally and spatially limited sampling campaign and actual average long-term exposures may be higher or lower.

## HEALTH IMPLICATIONS

### ***Overview for identifying contaminants of concern and evaluating risk***

To evaluate EtO exposures near Sterigenics, ATSDR considered its own health-based comparison values as well as those published by other agencies. ATSDR uses comparison values for screening purposes to determine whether a pollutant should be evaluated further. A CV was identified for both an intermediate exposure duration (for non-cancer evaluation) as well as for a long-term (chronic) exposure duration (for which we considered both cancer and non-cancer health effects). In this evaluation, the air sampling results were compared to the ATSDR Cancer Risk Evaluation Guide (CREG) and environmental media evaluation guide (EMEG) and California EPA Reference Exposure Level (REL) for EtO.

- ***ATSDR CREGs*** are estimates of the concentrations of a carcinogen at which there is an elevated risk for one additional case of cancer in one million people exposed over a lifetime. ATSDR's CREG for EtO is calculated from the current U.S. EPA's adult-based inhalation unit risk value ( $0.003 (\mu\text{g}/\text{m}^3)^{-1}$ ) and is based on U.S. EPA evaluations and assumptions about hypothetical cancer risks at low levels of exposure. ATSDR's CREG for EtO is  $0.00021 \mu\text{g}/\text{m}^3$ .
- ***ATSDR inhalation minimal risk levels (MRL)/EMEGs*** are estimates of the concentrations of pollutants calculated that anyone could be exposed to where health effects are unlikely, based on chronic, intermediate, and acute exposures (those occurring longer than 365 days, between 14-365 days, and 14 days of exposure or less, respectively). For EtO, ATSDR only has an intermediate EMEG of  $160 \mu\text{g}/\text{m}^3$  (ATSDR, 1990).
- ***California RELs*** are concentrations that are unlikely to result in adverse non-cancer health effects. The chronic California REL for EtO is  $30 \mu\text{g}/\text{m}^3$  (California EPA, 2008).

All 5-year modeled and 12-hour measured averages exceeded the ATSDR CREG. Only maximum modeled concentrations exceeded intermediate or chronic non-cancer screening values. The following sections evaluate chronic non-cancer and cancer risks further.

### ***Ethylene oxide properties***

Ethylene oxide is a highly flammable gas that is highly reactive with nucleophilic substances such as water, alcohols, halides, amines, and sulfhydryl compounds. It is used as an intermediate in the production of ethylene glycol and surfactants as well as a fumigant for sterilizing foods and heat-sensitive medical equipment.

EtO is highly reactive, readily absorbed, and easily distributed in the human body. The absolute odor threshold has been reported in several studies to be about 470 milligrams per cubic meter ( $\text{mg}/\text{m}^3$ )

(or 470,000  $\mu\text{g}/\text{m}^3$ ), with acute health effects possible in the range of the odor threshold (NRC, 2010). Chronic exposures can result somatic cell damage at much lower concentrations (California EPA, 2008). EtO is mutagenic and causes chromosome damage in many species, including humans. EtO exposure has widely been studied in scientific literature and its adverse health impacts are well understood. The carcinogenic effects of EtO have been documented in human and animal studies (U.S. EPA 2016).

### ***Acute and intermediate exposure and health effects***

Acute and intermediate effects have mostly been documented in hospital workers or in other occupational settings that include sterilizing chambers. Short-term exposure (minutes to weeks or months) above the odor threshold of 470  $\text{mg}/\text{m}^3$  (into the thousands of  $\text{mg}/\text{m}^3$ ) include primarily neurological effects (headache, dizziness, nausea, lethargy, fatigue, muscle weakness, numbness, memory loss, incoordination, etc.), respiratory irritation (irritation of the nasal cavity, sinuses, coughing, shortness of breath, wheezing, and bronchial constriction and hyperreactivity), excessive thirst and dry mouth, and gastrointestinal effects (vomiting, diarrhea, stomach spasms, etc.). Some studies reported skin rashes with short-term exposures (NRC, 2010).

All studies with documented health effects summarized above had substantially higher EtO concentrations than what was observed in measured and modeled data in this assessment. ATSDR does not have an acute health-based comparison value but does have an intermediate-duration health-based comparison value of 160  $\mu\text{g}/\text{m}^3$ . No measured data and only the maximum 1-hour modeled concentration of EtO exceeded this value and modeled and measured concentrations of EtO in this investigation were well below the odor threshold. Thus, it is unlikely that the non-cancer health effects noted above would occur in the general or off-site worker populations.

### ***Chronic exposure and health effects***

#### **Cancer effects**

The U.S. EPA IRIS released an “Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide” in December 2016. This evaluation summarizes the evidence that EtO is “carcinogenic to humans” through a mutagenic mode of action (MOA) and derives an inhalation unit risk value for EtO (U.S. EPA, 2016). Many studies have identified the genotoxic potential and mutagenic mode of action of EtO exposure via inhalation. There is clear evidence from multiple studies that EtO causes chromosomal aberrations, sister chromatic exchanges, and micronuclei in peripheral blood lymphocytes and bone marrow cells. Chromosomal aberrations and micronucleus frequency have been linked to increased risk of cancer in a number of large human studies (Jinot et al., 2017). Mice and rats exposed to EtO demonstrate cancers of the lymphohematopoietic system (cells involved in the production of lymphocytes and cells of blood, bone marrow, spleen, lymph nodes, and thymus), brain, lung, connective tissue, uterus, and mammary gland.

In humans, an increased incidence and mortality of breast and lymphohematopoietic system cancers have been observed in workers in the EtO manufacturing and in sterilizing facilities (U.S. EPA, 2016). U.S. EPA identified six studies evaluating breast cancer in women, with the largest being a study from the National Institute of Occupational Safety and Health (NIOSH) of over 18,000 workers (45% male, 55% female) in 14 commercial sterilization plants. The NIOSH study reported statistically significant

exposure-response relationships for breast cancer incidence and mortality (Steenland et al., 2004 and Steenland et al., 2004). From assessing these studies, U.S. EPA (2016) determined that there is sufficient evidence of a causal relationship between EtO exposure and breast cancer in women.

U.S. EPA used the cancer incidence data from the NIOSH study, using individual exposure estimates for 17,530 workers from 13 plants, to calculate an inhalation unit risk value. A linear low-dose extrapolation of the lowest effective concentration (LEC; defined here as the lower 95% confidence limit on the EC<sub>01</sub>, the estimated effective concentration associated with 1% extra risk) for lymphoid cancer was calculated as  $2.9 \times 10^{-3}$  per  $\mu\text{g}/\text{m}^3$ . Using the same approach, the lifetime unit risk for breast cancer was calculated as  $8.1 \times 10^{-4}$  per  $\mu\text{g}/\text{m}^3$ . Combining the risk for lymphoid and breast cancers in females U.S. EPA adopted an inhalation unit risk of  $2.99 \times 10^{-3}$  per  $\mu\text{g}/\text{m}^3$  (rounded to  $3.0 \times 10^{-3}$  per  $\mu\text{g}/\text{m}^3$ ). These adult-exposure only unit risk estimates were then rescaled to a lifetime, using age-dependent adjustment factors (ADAF). ADAFs are used to incorporate the greater risk of early life exposure to chemicals that have a mutagenic MOA. When applying the ADAFs, EPA calculated an inhalation unit risk value over a 70-year lifetime of  $5.0 \times 10^{-3}$  per  $\mu\text{g}/\text{m}^3$  (U.S. EPA, 2016). Cancer risk from measured and modeled EtO concentrations are estimated by multiplying the IUR by the EtO concentrations.

#### *U.S. EPA Cancer Risk Estimates Reviewed by ATSDR*

U.S. EPA Region 5 air modelers estimated cancer risk assuming a 70-year lifetime from measured and modeled data. Based on modeled EtO concentrations at over 882 specific locations around the Sterigenics facility, U.S. EPA used the 5-year average EtO concentrations to calculate lifetime cancer risks between  $1.3 \times 10^{-4}$  to  $6.7 \times 10^{-2}$ , with a geometric mean risk of  $9.1 \times 10^{-4}$ . Even though cancer risks are not generally calculated for short term exposures, the estimated cancer risks associated with the *measured* EtO air concentration (19 samples collected for 12 hours each) were similar (range:  $7.9 \times 10^{-4}$  to  $4.5 \times 10^{-2}$ , geometric mean:  $7.7 \times 10^{-3}$ ; Table 3). Note that these cancer risks were calculated using the lifetime ADAF-adjusted IUR of  $5.0 \times 10^{-3}$  per  $\mu\text{g}/\text{m}^3$ .

**Table 3. Range of measured and modeled EtO concentrations: U.S. EPA Cancer Risk Estimates**

Statistics	Modeled 5-year ( $\mu\text{g}/\text{m}^3$ )	Modeled cancer risk range	12-hour samples ( $\mu\text{g}/\text{m}^3$ )	Measured cancer risk range*
Minimum	0.03	1.3E-04	0.16	7.9E-04
Maximum	13.32	6.7E-02	4.34	4.5E-02
Mean	0.32	1.6E-03	1.04	1.4E-02
Geometric Mean	0.18	9.1E-04	0.61	7.7E-03

\*Cancer risk was calculated to estimate what long term exposures to the 12-hour concentration could look like if sustained long term and does not represent actual exposures.

#### *Cancer Risk Estimates Calculated by ATSDR*

For ATSDR assessments, the reasonable maximum exposure (RME) scenario for residential exposure duration is 33 years over a lifetime of 78 years, so ATSDR calculated an IUR based on 33-year residential exposure using ADAFs. As mentioned previously, ATSDR's RME exposure point concentration (EPC) of  $2.1 \mu\text{g}/\text{m}^3$  was used as a reasonable estimate of exposure for the most exposed individual in the community. This EPC is the maximum residential sample concentration of EtO in the May 2018 data collection period. Given these assumptions, the cancer risk for this residential sample

location is  $6.4 \times 10^{-3}$ —an additional lifetime risk of 6.4 cancers in a population of 1,000 residents who could be exposed to EtO emissions from Sterigenics. This cancer risk exceeds U.S. EPA’s decision-making cancer risk range of  $1.0 \times 10^{-6}$  to  $1.0 \times 10^{-4}$ , and adds to the lifetime background cancer risk of an average American of 1 in 3 people (American Cancer Society, 2018).

**Table 4. Site-specific ADAF calculations for residential exposure\***

Age Range	ADAF	U.S. EPA unadjusted IUR	EPC ( $\mu\text{g}/\text{m}^3$ )	Duration Adjustment	Partial Risk
0 to <2 yrs	10	$2.99 \times 10^{-3}$	2.1	2 years/78 years	$1.6 \times 10^{-3}$
2 to <16 yrs	3	$2.99 \times 10^{-3}$	2.1	14 years/78 years	$3.4 \times 10^{-3}$
16 to 33 yrs	3	$2.99 \times 10^{-3}$	2.1	17 years/78 years	$1.4 \times 10^{-3}$
<b>Lifetime Risk</b>					<b><math>6.4 \times 10^{-3}</math></b>

\*Cancer risk was calculated to estimate what long term exposures to the 12-hour concentration could look like if sustained long term and does not represent actual exposures.

Likewise, ATSDR assumed the maximum commercial 12-hour sample concentration in commercial sample locations of  $9.1 \mu\text{g}/\text{m}^3$  to represent RME occupational exposures to workers in nearby facilities. Note that workers at the Sterigenics facility would be covered under the Occupational Safety and Health Administration (OSHA) EtO standard (29 CFR 1910.1047). For the off-site worker scenario, ATSDR assumed an 8.5-hour workday, 250 days a year, for 25 years (ATSDR, 2016), yielding an exposure factor (EF) of 0.08.

$$EF_{\text{cancer, chronic}} = \frac{8.5 \frac{\text{hr}}{\text{d}} \times 5 \frac{\text{d}}{\text{wk}} \times 50 \frac{\text{wk}}{\text{yr}} \times 25 \text{ yr}}{24 \frac{\text{hr}}{\text{d}} \times 7 \frac{\text{d}}{\text{wk}} \times 52.14 \frac{\text{wk}}{\text{yr}} \times 78 \text{ yr}} = 0.08$$

Cancer risk for workers can be calculated by multiplying the long-term air concentration by the IUR, adjusting the duration of exposure as appropriate using the exposure factor calculation, above:

$$\text{Cancer risk} = \text{IUR} \times \text{EPC} (\mu\text{g}/\text{m}^3) \times \text{EF}$$

For the maximum commercial concentration of  $9.1 \mu\text{g}/\text{m}^3$ , this risk equation yields a lifetime occupational cancer risk of  $2.1 \times 10^{-3}$ , or an increased risk of cancer for 2.1 people in a population of 1,000 workers from chronic exposures to Sterigenics emissions:

$$\text{Cancer risk}_{\text{occupational}} = 0.00299 \times 9.1 \mu\text{g}/\text{m}^3 \times 0.08 = \mathbf{2.1 \times 10^{-3}}$$

While a more complete database from which to characterize exposure is preferable, we used U.S. EPA’s limited data for the Sterigenics investigation and applied the standard ATSDR evaluation process. Note that in both ATSDR calculations, we made a very conservative assumption that a 12-hour sample represents long term exposure. We felt this assumption was warranted because the measured and modeled concentrations demonstrated consistency and provided support that this range of exposure is possible in the area surrounding Sterigenics.

### Non-cancer effects

Workers exposed to ethylene oxide over a long-term duration experienced similar health effects to those exposed over shorter durations (California EPA, 2008). Workers exposed to levels of EtO at 8,500  $\mu\text{g}/\text{m}^3$  and higher over an average of 5-6.5 years demonstrated cognitive and motor impairment compared to unexposed controls. At lower levels of EtO exposure (145-300  $\mu\text{g}/\text{m}^3$ ), studies have shown evidence of hemoglobin adducts, DNA damage effects (i.e. sister chromatid exchanges), and hematological effects (i.e. increases in leukocytes and decreases in neutrophil counts; decreases in hematocrit and hemoglobin) (California EPA, 2008). No measured EtO concentrations from the residential or occupational sampling approached or exceeded effect levels in the long-term modeling estimates or the 12-hour samples being used as chronic exposure surrogates, therefore, non-cancer health effects are not expected. However, air sampling in this effort was extremely limited.

### **LIMITATIONS**

ATSDR made several assumptions as part of this assessment that could lead to the over or underestimation of risk. Some limitations of this assessment include:

1. To calculate risks, ATSDR assumed that the concentrations measured during this assessment will continue, unchanged if no actions are taken, over 33 years for residents, and 25 years for workers.
2. ATSDR assumed that the very limited sampling investigation of 26 discrete locations over 2 days throughout the community represents typical exposure conditions from Sterigenics EtO emissions. Only one 12-hour residential sample was collected, and that sample was used to represent the RME residential chronic exposure estimate. EtO concentrations from grab samples at one other residential location were slightly higher than the 12-hour averaged sample collected at this property.
3. ATSDR assumed that the highest EtO concentration in the commercial area surrounding Sterigenics represents worst case off-site worker exposures. This is likely underestimating worker exposures for some employees in this area.
4. Due to a lack of long term sampling, the temporal trends of EtO emissions could not be evaluated. Fluctuations of seasons that affect temperatures, barometric pressure, wind speed and direction, and other potential factors that could influence the transport of EtO into the surrounding community were not assessed.

Despite these limitations, ATSDR acknowledges that the U.S. EPA modeling demonstrates similar concentration ranges to community air measurements. Thus, ATSDR believes the exposure estimates assumed in this assessment are reasonable. Historical emissions were higher before a substantial drop in 1999 with the construction of aeration rooms in Building 1. EtO cancer risks may have been substantially greater for the 14 years the facility operated before these emission controls were implemented, but historical risk cannot be evaluated with available emissions data.

**Conclusions:**

U.S. EPA asked ATSDR to answer the following question: *"If modeled and measured ethylene oxide concentrations represent long term conditions, would they pose a public health problem for people living and working in Willowbrook?"* U.S. EPA provided modeled and measured data for ATSDR to evaluate and render a health opinion.

It is ATSDR's conclusion that the data U.S. EPA provided suggests that residents and workers are exposed to elevated airborne EtO concentrations from facility emissions. It is difficult to assess long-term public health implications from facility emissions because there has been no historical air monitoring in the community. ATSDR assumed that these data represent long term exposures for area residents and workers. Specifically, ATSDR concludes the following:

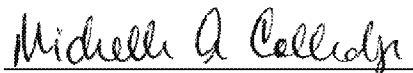
- 1) If measured and modeled data represent typical EtO ambient concentrations in ambient air, *an elevated cancer risk exists* for residents and off-site workers in the Willowbrook community surrounding the Sterigenics facility. These elevated risks *present a public health hazard to these populations*.
- 2) Measured and modeled ethylene oxide concentrations in ambient air indicate that non-cancer health effects are unlikely for residents and off-site workers in the Willowbrook community surrounding the Sterigenics facility.

**Recommendations:**

- 1) ATSDR recommends that Sterigenics take immediate action to reduce EtO emissions at this facility.
- 2) ATSDR recommends that U.S. EPA work with the Sterigenics facility to initiate long-term air monitoring as soon as possible to measure ambient air levels of EtO. Ongoing air monitoring can demonstrate the effectiveness of actions taken by the company to reduce emissions and subsequent exposures in the community.
- 3) ATSDR recommends that IDPH investigate whether there are elevated cancers in the population surrounding the Sterigenics facility that are consistent with those associated with chronic EtO exposures.

Please do not hesitate to contact ATSDR Region 5 to discuss this assessment further or to request further public health assistance.

Sincerely,



Michelle Colledge, MPH, PhD  
Environmental Health Scientist  
Agency for Toxic Substances and Disease Registry  
Division of Community Health Investigations  
Central Branch, Region 5

CC:

Ken Runkle, IDPH

Aaron Martin, IDPH

Kathryn Siegel, U.S. EPA

Margaret Sieffert, U.S. EPA

Alexis Cain, U.S. EPA

Mark Johnson, ATSDR/ DCHI/CB

Rick Gillig, ATSDR/ DCHI/CB

Tina Forrester, ATSDR/ DCHI/OD

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## Mahgoub, Gaida

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**From:** Wayland, Richard  
**Sent:** Thursday, October 18, 2018 11:11 AM  
**To:** Koerber, Mike  
**Cc:** Davis, Alison; Rimer, Kelly; Bremer, Kristen  
**Subject:** Re: Sterigenics US LLC

He called me again yesterday and I told him Clint had reached out to his boss in IL EPA and that further conversations would not come until after their boss had reviewed the 1-pager we sent up to Clint. So the ball is back in their court at this point. No action for us at this point.

Chet

Richard A. "Chet" Wayland  
Sent from my iPhone

On Oct 18, 2018, at 8:19 AM, Koerber, Mike <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)> wrote:

Not sure we do to anything more.

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**From:** Davis, Alison  
**Sent:** Thursday, October 18, 2018 7:42 AM  
**To:** Wayland, Richard <[Wayland.Richard@epa.gov](mailto:Wayland.Richard@epa.gov)>; Koerber, Mike <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)>; Rimer, Kelly <[Rimer.Kelly@epa.gov](mailto:Rimer.Kelly@epa.gov)>; Bremer, Kristen <[Bremer.Kristen@epa.gov](mailto:Bremer.Kristen@epa.gov)>  
**Subject:** RE: Sterigenics US LLC

All – what is the status on this response? Do we still need to reach out? Thanks.  
-Alison

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**From:** Rimer, Kelly  
**Sent:** Friday, October 12, 2018 9:49 AM  
**To:** Tsirigotis, Peter <[Tsirigotis.Peter@epa.gov](mailto:Tsirigotis.Peter@epa.gov)>; Wayland, Richard <[Wayland.Richard@epa.gov](mailto:Wayland.Richard@epa.gov)>  
**Cc:** Koerber, Mike <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)>; Cozzie, David <[Cozzie.David@epa.gov](mailto:Cozzie.David@epa.gov)>; Weinstock, Lewis <[Weinstock.Lewis@epa.gov](mailto:Weinstock.Lewis@epa.gov)>; Shappley, Ned <[Shappley.Ned@epa.gov](mailto:Shappley.Ned@epa.gov)>; Davis, Alison <[Davis.Alison@epa.gov](mailto:Davis.Alison@epa.gov)>  
**Subject:** RE: Sterigenics US LLC

All,

If you all need OGC on this, Sonja Rodman is available to assist.

Alison and I contacted OGC yesterday (Lea) and asked for an attorney to be assigned to the EtO follow-up. Lea named Sonja.

Thanks,  
Kelly

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**From:** Tsirigotis, Peter  
**Sent:** Thursday, October 11, 2018 2:50 PM  
**To:** Wayland, Richard <[Wayland.Richard@epa.gov](mailto:Wayland.Richard@epa.gov)>  
**Cc:** Koerber, Mike <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)>; Cozzie, David <[Cozzie.David@epa.gov](mailto:Cozzie.David@epa.gov)>; Rimer, Kelly <[Rimer.Kelly@epa.gov](mailto:Rimer.Kelly@epa.gov)>; Weinstock, Lewis <[Weinstock.Lewis@epa.gov](mailto:Weinstock.Lewis@epa.gov)>; Shappley, Ned <[Shappley.Ned@epa.gov](mailto:Shappley.Ned@epa.gov)>  
**Subject:** Re: Sterigenics US LLC

We should also fold in Clint at the right point.

On Oct 11, 2018, at 2:33 PM, Wayland, Richard <[Wayland.Richard@epa.gov](mailto:Wayland.Richard@epa.gov)> wrote:

Got a call from this gentleman today with Illinois EPA general counsel. Maybe we can chat tomorrow about how best to respond and who should be included.

Richard A. "Chet" Wayland | Director | Air Quality Assessment Division - Mail Code C304-02 |  
Office of Air Quality Planning & Standards | U.S. Environmental Protection Agency | Research  
Triangle Park, NC 27711 | Desk: 919-541-4603 | Cell: 919-606-0548 |

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**From:** Kim, John J. [<mailto:John.J.Kim@Illinois.gov>]  
**Sent:** Thursday, October 11, 2018 2:25 PM  
**To:** Wayland, Richard <[Wayland.Richard@epa.gov](mailto:Wayland.Richard@epa.gov)>  
**Subject:** Sterigenics US LLC

Thank you for taking time to speak with me on the phone today. To recap, my request was for a phone call with you or your staff so that interested government representatives in Illinois (from the Illinois EPA and the Illinois Attorney General's Office) can better understand what the scope and parameters of modeling to be done based on recent stack test results from the Sterigenics facility in Willowbrook, Illinois.

We are interested in learning about what goals are being pursued, estimates of timelines, relation of modeling to ambient air modeling, and related subjects. This would help greatly with the State's efforts to effectively respond to the conditions at the Sterigenics facility in an appropriate manner.

I look forward to hearing from you.

John K.

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John J. Kim  
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Illinois Environmental Protection Agency  
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## Mahgoub, Gaida

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**From:** Mckelvey, Laura  
**Sent:** Wednesday, February 13, 2019 2:23 PM  
**To:** EtO;Koerber, Mike;Weinstock, Lewis;Davis, Alison;Bremer, Kristen;Wilson, Holly;Long, Pam  
**Subject:** FW: Follow up

**From:** Jennifer McConahy <jgleason721@gmail.com>  
**Sent:** Tuesday, February 12, 2019 4:45 PM  
**To:** Mckelvey, Laura <Mckelvey.Laura@epa.gov>  
**Subject:** Re: Follow up

Hi Laura,  
Can I get the usage numbers? We have pieces missing in our own analysis and this would be helpful.  
Jen

On Tue, Feb 12, 2019 at 12:02 PM Mckelvey, Laura <Mckelvey.Laura@epa.gov> wrote:

Sorry Jen,

I got caught in a totally different issue this morning and forgot. Here's the language of the Act that discusses data collection for rulemaking as you requested.

<https://www.govinfo.gov/content/pkg/USCODE-2013-title42/html/USCODE-2013-title42-chap85-subchapl-partA-sec7414.htm>

I was able to ask Mike this morning and he said the meeting went well and the facility was cooperative and provided the data that we and the state requested.

Thanks

Laura

**From:** Jennifer McConahy <jgleason721@gmail.com>  
**Sent:** Tuesday, February 12, 2019 12:57 PM  
**To:** Mckelvey, Laura <Mckelvey.Laura@epa.gov>  
**Subject:** Follow up

Hi-

Checking to see if there were any updates from your meeting. I was also hoping to get the specific wording of 114 letter. Thank you

Jen

**Mahgoub, Gaida**

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**From:** Davis, Alison  
**Sent:** Wednesday, October 17, 2018 5:07 PM  
**To:** Koerber, Mike  
**Cc:** Rimer, Kelly;Bremer, Kristen  
**Subject:** EtO mailbox - update

Mike – Nancy Grantham has offered to have her intern respond from the EtO mailbox. (The intern also tracks emails to the Administrator.) I am taking her up on that, so no need to raise that with Clint.

I would like to make sure he's aware of the OCIR approach - we review, they answer – and to be sure he is OK with that.

Thanks

## **Mahgoub, Gaida**

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**From:** Davis, Alison  
**Sent:** Thursday, November 8, 2018 10:50 AM  
**To:** Whitlow, Jeff  
**Subject:** RE: Confidential

OK. I would prefer Tuesday, if we have any say. Tomorrow is going to be challenging for reaching people. We are super thing, staffing wise

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**From:** Whitlow, Jeff  
**Sent:** Thursday, November 08, 2018 10:01 AM  
**To:** Davis, Alison <Davis.Alison@epa.gov>  
**Subject:** RE: Confidential

He's checking to see if Wehrum wants to send it. Maybe tomorrow or Tuesday.

Jeff Whitlow  
Director, Central Operations and Resources  
Office of Air Quality Planning and Standards  
Office of Air and Radiation  
U.S. Environmental Protection Agency

p: 919.541.5523

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**From:** Davis, Alison  
**Sent:** Thursday, November 8, 2018 9:58 AM  
**To:** Whitlow, Jeff <Whitlow.Jeff@epa.gov>  
**Subject:** RE: Confidential

Any sense of when Peter plans to send the email?

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**From:** Whitlow, Jeff  
**Sent:** Thursday, November 08, 2018 9:53 AM  
**To:** Davis, Alison <Davis.Alison@epa.gov>  
**Subject:** FW: Confidential

No go for today.

Jeff Whitlow  
Director, Central Operations and Resources  
Office of Air Quality Planning and Standards  
Office of Air and Radiation

U.S. Environmental Protection Agency

p: 919.541.5523

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**From:** Davis, Alison

**Sent:** Thursday, November 8, 2018 9:32 AM

**To:** Whitlow, Jeff <[Whitlow.Jeff@epa.gov](mailto:Whitlow.Jeff@epa.gov)>

**Subject:** Confidential

I'd like to tell my team at noon. What do you think?

## Mahgoub, Gaida

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**From:** Tsirigotis, Peter  
**Sent:** Tuesday, November 13, 2018 4:01 PM  
**To:** Scott Monroe (Monroe.Scott@epa.gov)  
**Subject:** FW: OAQPS Deputy Director

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**From:** Wehrum, Bill  
**Sent:** Tuesday, November 13, 2018 2:22 PM  
**To:** OAQPS Group <OAQPS\_Group@epa.gov>; Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>; Woods, Clint <woods.clint@epa.gov>; Harlow, David <harlow.david@epa.gov>; Dominguez, Alexander <dominguez.alexander@epa.gov>; Shaw, Betsy <Shaw.Betsy@epa.gov>; Lewis, Josh <Lewis.Josh@epa.gov>; Atkinson, Emily <Atkinson.Emily@epa.gov>; Rakosnik, Delaney <rakosnik.delaney@epa.gov>; Dunham, Sarah <Dunham.Sarah@epa.gov>; Grundler, Christopher <grundler.christopher@epa.gov>; Edwards, Jonathan <Edwards.Jonathan@epa.gov>; Shoaff, John <Shoaff.John@epa.gov>; Air Division Directors and Deputies <Air\_Division\_Directors\_and\_Deputies@epa.gov>  
**Subject:** OAQPS Deputy Director

I am very happy to announce that Mike Koerber has been selected to be the Deputy Director for the Office of Air Quality Planning & Standards (OAQPS).

When Mike joined OAQPS as the associate director for policy, he had a reputation as an authority in air quality management and as someone who was widely respected by his state agency peers. If you've had the pleasure of working with Mike, you know this reputation is well deserved. I have been impressed with his breadth of knowledge, his ability to work with people on all sides of an issue, and his ability to manage multiple complex issues at the same time.

Mike began his career in EPA Region 5's Air and Radiation Division, where he did air quality modeling and developed several federal plans. He left EPA to serve as the director of the Lake Michigan Air Directors Consortium (LADCO), a position he held for more than 20 years. LADCO became known for its technical work to support state control plans for multiple air pollutants. Mike helped lead efforts to address cross-state air pollution in the eastern U.S.

As the OAQPS deputy, Mike will manage the OAQPS immediate office, including CORE and PACS. He also will work closely with the division directors on a variety of issues and projects, especially those involving multiple divisions or offices/regions. Current examples include NAAQS and regional haze implementation, addressing ethylene oxide emissions, and the review of the New Source Performance Standards for Residential Wood Heaters.

Please join me in congratulating Mike.

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Bill Wehrum  
Assistant Administrator  
Office of Air and Radiation  
U.S. Environmental Protection Agency  
(202) 564-7404

## **Mahgoub, Gaida**

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**From:** Bremer, Kristen  
**Sent:** Thursday, June 21, 2018 3:26 PM  
**To:** Davis, Alison  
**Subject:** Draft Sterigenics Website

<https://wcms.epa.gov/il/sterigenics-willowbrook-facility>

You will first need to log into Drupal. It's basically the Denka website.

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Kristen Bremer  
Policy Analysis & Communications  
U.S. EPA, Office of Air Quality Planning & Standards  
Email: [bremer.kristen@epa.gov](mailto:bremer.kristen@epa.gov)  
Phone: 919.541.9424  
Cell: 919.321.7652

## Mahgoub, Gaida

---

**From:** Davis, Alison  
**Sent:** Wednesday, November 7, 2018 2:06 PM  
**To:** Koerber, Mike  
**Subject:** RE: URGENT - Press Deadline 330 p.m.

Ex. 6 Personal Privacy (PP)

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**From:** Koerber, Mike  
**Sent:** Wednesday, November 07, 2018 2:06 PM  
**To:** Davis, Alison <Davis.Alison@epa.gov>  
**Subject:** Re: URGENT - Press Deadline 330 p.m.

We need to talk - what is your phone number?

Sent from my iPhone

On Nov 7, 2018, at 2:00 PM, Davis, Alison <Davis.Alison@epa.gov> wrote:

Kelly & Darcie

Jeff Kelley and John Konkus just called me. Michael Hawthorne is writing about the press release just issued (below). John would like us to answer this with a NATA process question – How NATA is put together, when the states review, etc. We can emphasize that information changes throughout this process.

Please let me know that you received this. Once we have the draft answer, we'll send to Clint for review before sending to Jeff & John.  
Thanks.

**From:** "LaPaille, Joe (Durbin)" <Joe\_LaPaille@durbin.senate.gov>  
**Subject:** DURBIN CALLS FOR INVESTIGATION INTO TRUMP ADMINISTRATION'S DELAY OF NOTIFYING LAKE COUNTY RESIDENTS ABOUT CANCER-CAUSING POLLUTION  
**Date:** November 7, 2018 at 11:52:04 AM CST  
**To:** "LaPaille, Joe (Durbin)" <Joe\_LaPaille@durbin.senate.gov>

<image001.png>

For Immediate Release  
November 7, 2018  
Contact: Emily Hampsten  
(202) 228-5643

## **DURBIN CALLS FOR INVESTIGATION INTO TRUMP ADMINISTRATION'S DELAY OF NOTIFYING LAKE COUNTY RESIDENTS ABOUT CANCER-CAUSING POLLUTION**

CHICAGO – U.S. Senator Dick Durbin (D-IL) today, in a letter to the Office of the Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA), called for an investigation into whether EPA followed proper protocols when critical health information about cancer-causing ethylene oxide (EtO) emissions at Medline Industries, Inc. and Vantage Specialty Chemicals, Inc. was withheld from Lake County, Illinois residents. Last week, the *Chicago Tribune* published a [story](#) that details how the two facilities in Lake County appear to emit cancer-causing emissions, yet the Trump Administration, along with Governor Rauner’s Administration, delayed giving this pertinent information to Illinoisans and still have not properly tested air quality in the area.

**“After the findings of the 2016 Integrated Risk Information System report that indicated ethylene oxide (EtO) is much more carcinogenic at lower concentrations than previously thought, EPA acknowledged the increased risks but did not inform residents in DuPage and Lake counties of facilities near them that use and emit EtO and how those emission could cause long-term health concerns,”** Durbin wrote. **“Withholding this vital public health information from the communities with potentially high EtO exposure is unacceptable. The residents need reassurance that the EPA has their best interests in mind and is taking the proper steps to ensure the air they breathe is clean.”**

Last week, Durbin, along with Senator Tammy Duckworth (D-IL) and Rep. Brad Schneider (D-IL-10), [pressed](#) the EPA to perform an in-depth investigation into EtO emissions at Medline Industries, Inc. and Vantage Specialty Chemicals, Inc. In addition, the members urged EPA to publish a timeline for when it will revise the current Clean Air Act (CAA) EtO standards to limit future emission to a level deemed safe by the 2016 Agency for Toxic Substances and Disease Registry and 2014 National Air Toxics Assessment (NATA) reports. These recent reports have shown that the existing standards need to be lowered to protect public health in communities across the county.

Additionally, Durbin, Duckworth, and Rep. Bill Foster (D-IL-11) have [requested](#) the EPA OIG to investigate if EPA complied with all statutory, regulatory, and policy requirements and protocols when it intentionally withheld critical health information from the public about carcinogenic air pollution from the Sterigenics facility in DuPage County, Illinois.

Durbin and Duckworth are set to meet with Andrew Wheeler, EPA Acting Administrator, in Washington, D.C., on Wednesday, November 14.

Full text of the letter is available [here](#) and below:

The Honorable Charles Sheehan  
Acting Inspector General  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460

Dear Acting Inspector General Sheehan,

We/I write to follow up on a request from November 1 and ask the Office of the Inspector General of the U.S. Environmental Protection Agency (EPA) to investigate if statutory authority and proper protocols were followed when critical health information about carcinogenic ethylene oxide pollution from two additional facilities—Medline Industries, Inc. in Waukegan and Vantage Specialty Chemicals, Inc. in Gurnee—was intentionally withheld from residents in Lake County, Illinois.

After the findings of the 2016 Integrated Risk Information System report that indicated ethylene oxide (EtO) is much more carcinogenic at lower concentrations than previously thought, EPA acknowledged the increased risks but did not inform residents in DuPage and Lake counties of facilities near them that use and emit EtO and how those emission could cause long-term health concerns. This news is especially concerning as Vantage Specialty Chemicals has not reported its most recent EtO emissions, as it is required to do, and previous reports show that Vantage released more EtO than both Sterigenics and Medline.

Withholding this vital public health information from the communities with potentially high EtO exposure is unacceptable. The residents need reassurance that the EPA has their best interests in mind and is taking the proper steps to ensure the air they breathe is clean.

For this reason, I ask you expand the scope of my previously requested investigation to include the facilities in Lake County. I/We look forward to your prompt response.

Sincerely,

-30-

## Mahgoub, Gaida

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**From:** Davis, Alison  
**Sent:** Sunday, August 19, 2018 2:29 PM  
**To:** Lassiter, Penny  
**Cc:** Koerber, Mike; Rimer, Kelly; Sasser, Erika  
**Subject:** Re: Updated - simple messages for risk communication

That's an important point, and one I'll try to work in. Perhaps we can add it as a Q at the end.

Alison Davis  
Senior Advisor for Public Affairs  
USEPA, Office of Air Quality Planning & Standards  
Research Triangle Park, NC 27711  
Tel. 919-541-7587

---

**From:** Lassiter, Penny  
**Sent:** Sunday, August 19, 2018 2:27 PM  
**To:** Davis, Alison  
**Cc:** Koerber, Mike; Rimer, Kelly; Sasser, Erika  
**Subject:** Re: Updated - simple messages for risk communication

Allison,

# Ex. 5 Deliberative Process (DP)

Sent from my iPhone

On Aug 19, 2018, at 2:23 PM, Davis, Alison <[Davis.Alison@epa.gov](mailto:Davis.Alison@epa.gov)> wrote:

Sure thing. Thanks!

Alison Davis  
Senior Advisor for Public Affairs  
USEPA, Office of Air Quality Planning & Standards  
Research Triangle Park, NC 27711  
Tel. 919-541-7587

**From:** Lassiter, Penny  
**Sent:** Sunday, August 19, 2018 2:21 PM  
**To:** Koerber, Mike  
**Cc:** Rimer, Kelly; Davis, Alison; Sasser, Erika  
**Subject:** Re: Updated - simple messages for risk communication

## Ex. 5 Deliberative Process (DP)

Sent from my iPhone

On Aug 19, 2018, at 1:38 PM, Koerber, Mike <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)> wrote:

## Ex. 5 Deliberative Process (DP)<sup>th</sup>

Mike

---

**From:** Rimer, Kelly  
**Sent:** Sunday, August 19, 2018 11:37 AM  
**To:** Davis, Alison <[Davis.Alison@epa.gov](mailto:Davis.Alison@epa.gov)>; Koerber, Mike <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)>; Sasser, Erika <[Sasser.Erika@epa.gov](mailto:Sasser.Erika@epa.gov)>; Lassiter, Penny <[Lassiter.Penny@epa.gov](mailto:Lassiter.Penny@epa.gov)>  
**Subject:** RE: Updated - simple messages for risk communication

I like your edits to my edits. I found and fixed one typo – didn't rename the file.

---

**From:** Davis, Alison  
**Sent:** Sunday, August 19, 2018 11:31 AM  
**To:** Rimer, Kelly <[Rimer.Kelly@epa.gov](mailto:Rimer.Kelly@epa.gov)>; Koerber, Mike <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)>; Sasser, Erika <[Sasser.Erika@epa.gov](mailto:Sasser.Erika@epa.gov)>; Lassiter, Penny <[Lassiter.Penny@epa.gov](mailto:Lassiter.Penny@epa.gov)>  
**Subject:** Re: Updated - simple messages for risk communication

One edit to your edit to further simplify

Alison Davis  
Senior Advisor for Public Affairs  
USEPA, Office of Air Quality Planning & Standards  
Research Triangle Park, NC 27711  
Tel. 919-541-7587

---

**From:** Rimer, Kelly  
**Sent:** Sunday, August 19, 2018 11:28 AM  
**To:** Davis, Alison; Koerber, Mike; Sasser, Erika; Lassiter, Penny  
**Subject:** RE: Updated - simple messages for risk communication

Looks good. A few small suggestions.

I did try to help clarify the 'emit' issue. But I may have gummed up the works more...SPPD would need to look at what I wrote.

Kelly

---

**From:** Davis, Alison  
**Sent:** Sunday, August 19, 2018 9:03 AM  
**To:** Koerber, Mike <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)>; Rimer, Kelly <[Rimer.Kelly@epa.gov](mailto:Rimer.Kelly@epa.gov)>; Sasser, Erika <[Sasser.Erika@epa.gov](mailto:Sasser.Erika@epa.gov)>; Lassiter, Penny <[Lassiter.Penny@epa.gov](mailto:Lassiter.Penny@epa.gov)>  
**Subject:** Updated - simple messages for risk communication

Updated based on Friday's key messages. Suggestions for simplifying? Note that the word "emissions" often trips things into the "too complex" end of things.

Alison Davis  
Senior Advisor for Public Affairs  
USEPA, Office of Air Quality Planning & Standards  
Research Triangle Park, NC 27711  
Tel. 919-541-7587

<EtO Simple Messages for Outreach.DRAFT INTERNAL V3 updated 8.19.18KR.AD MK.docx>

## Mahgoub, Gaida

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**From:** Lassiter, Penny  
**Sent:** Monday, July 30, 2018 12:17 PM  
**To:** Lavoie, Tegan;Caparoso, Jennifer  
**Cc:** Brenda Shine  
**Subject:** FW: re MON

See below. I had talked to Leslie about engaging the ACC members that comprise their Ethylene Oxide Working Group to talk about what EO practices, emissions and controls are going on in MON, HON and PEPO categories. I think she just heard MON.

### *Penny Lassiter*

Group Leader  
Refining and Chemicals Group  
Sector Policies and Programs Division  
Office of Air Quality Planning and Standards  
U.S. Environmental Protection Agency  
Mail Code: E143-01  
Research Triangle Park, NC 27711  
(919) 541-5396  
lassiter.penny@epa.gov

---

**From:** Hulse, Leslie [mailto:Leslie\_Hulse@americanchemistry.com]  
**Sent:** Friday, July 27, 2018 1:55 PM  
**To:** Lassiter, Penny <Lassiter.Penny@epa.gov>  
**Subject:** re MON

Penny,

Per your request for a meeting to discuss MON issues related to EO, I understand that there is a face-to-face meeting already scheduled with your staff in RTP on August 2<sup>nd</sup>. I know my colleague Brendan is planning to attend, along with some member company reps. I think the meeting is at 2pm. I will not be there in person, but I can call-in if desired, or needed.

Leslie

**Leslie A. Hulse** | American Chemistry Council  
Assistant General Counsel  
[leslie\\_hulse@americanchemistry.com](mailto:leslie_hulse@americanchemistry.com)  
700 2<sup>nd</sup> Street, NE | Washington, DC | 20002  
O: (202) 249-6131  
[www.americanchemistry.com](http://www.americanchemistry.com)

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## Mahgoub, Gaida

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**From:** Sasser, Erika  
**Sent:** Thursday, June 21, 2018 8:12 PM  
**To:** Davis, Alison;Smith, Darcie;Langdon, Robin;Rimer, Kelly  
**Subject:** Fwd: Draft news release for Sterigenic

Sent from my iPhone

Begin forwarded message:

**From:** "Nam, Ed" <nam.ed@epa.gov>  
**Date:** June 21, 2018 at 7:08:18 PM EDT  
**To:** "Sasser, Erika" <Sasser.Erika@epa.gov>  
**Subject:** FW: Draft news release for Sterigenic

Erika,

Sorry I've been tied up all afternoon. I'm guessing you are out of the office by now, but I wanted to send you the latest press release – with some recent edits.

Katie sent you the recent website (FAQ), but we are also looking to put together another internal FAQ too.

Thanks,  
-Ed

*Here is a draft of the news release we're planning to issue at noon tomorrow.*

**DRAFT // EPA FINDS HIGH ELEVATED LEVELS OF CANCER-CAUSING POLLUTANT IN WILLOWBROOK, ILL.**

**Ex. 5 Deliberative Process (DP)**

# Ex. 5 Deliberative Process (DP)

###

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**Jeff Kelley**

*Director, Office of External Communications*

*U.S. EPA Region 5*

*ph: 312-353-1159*

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## **Mahgoub, Gaida**

---

**From:** Lassiter, Penny  
**Sent:** Wednesday, August 8, 2018 3:38 PM  
**To:** Caparoso, Jennifer  
**Subject:** latest EtO pager  
**Attachments:** EtO regulatory approach8.9.18pager pel.docx

### ***Penny Lassiter***

Group Leader  
Refining and Chemicals Group  
Sector Policies and Programs Division  
Office of Air Quality Planning and Standards  
U.S. Environmental Protection Agency  
Mail Code: E143-01  
Research Triangle Park, NC 27711  
(919) 541-5396  
lassiter.penny@epa.gov

## Mahgoub, Gaida

---

**From:** Lassiter, Penny  
**Sent:** Tuesday, August 21, 2018 6:33 PM  
**To:** Davis, Alison  
**Cc:** Morales, Mariel; Bremer, Kristen  
**Subject:** RE: Need help with two questions

1.

2.

# Ex. 5 Deliberative Process (DP)

### *Penny Lassiter*

Group Leader  
Refining and Chemicals Group  
Sector Policies and Programs Division  
Office of Air Quality Planning and Standards  
U.S. Environmental Protection Agency  
Mail Code: E143-01  
Research Triangle Park, NC 27711  
(919) 541-5396  
lassiter.penny@epa.gov

---

**From:** Davis, Alison  
**Sent:** Tuesday, August 21, 2018 6:07 PM  
**To:** Lassiter, Penny <Lassiter.Penny@epa.gov>  
**Cc:** Morales, Mariel <Morales.Mariel@epa.gov>; Bremer, Kristen <Bremer.Kristen@epa.gov>  
**Subject:** Need help with two questions

Here they are. Suggested answers? Thank you.

# **Ex. 5 Deliberative Process (DP)**

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Alison Davis  
Acting Director  
Policy Analysis & Communications Staff  
US EPA, Office of Air Quality Planning & Standards  
Research Triangle Park, NC 27711  
Desk: 919-541-7587  
Mobile: 919-624-0872

## **Mahgoub, Gaida**

---

**From:** Lassiter, Penny  
**Sent:** Monday, September 10, 2018 11:41 AM  
**To:** Caparoso, Jennifer  
**Subject:** Accepted: EtO at chemical facilities in Region V

## Mahgoub, Gaida

---

**From:** Lassiter, Penny  
**Sent:** Wednesday, August 22, 2018 12:43 PM  
**To:** Caparoso, Jennifer  
**Subject:** FW: Modeling Results

Jennifer,

I'm not 100% sure what he's asking for. If he's talking about his facilities that show up in a NATA census track at potential risk > 100 in a million, I don't know that we have any facility-specific modeling because I don't believe these are MON. Or, is he asking to see what we modeled for his facilities subject to MON?

Anyway, any facility-specific modeling information would need to come from ATAG.

Penny Lassiter  
Group Leader  
Refining and Chemicals Group  
Sector Policies and Programs Division  
Office of Air Quality Planning and Standards U.S. Environmental Protection Agency Mail Code: E143-01 Research  
Triangle Park, NC 27711  
(919) 541-5396  
lassiter.penny@epa.gov

-----Original Message-----

From: Gossett, Stephen R [mailto:srgosset@eastman.com]  
Sent: Wednesday, August 22, 2018 9:32 AM  
To: Lassiter, Penny <Lassiter.Penny@epa.gov>  
Subject: Modeling Results

Hello Penny. Could EPA send me the modeling results for our 2 facilities?

Sent from my iPhone

## **Mahgoub, Gaida**

---

**From:** Cozzie, David  
**Sent:** Wednesday, September 26, 2018 9:03 AM  
**To:** Lassiter, Penny  
**Subject:** Don't send the 114 letter until we talk

Sent from my iPhone

## Mahgoub, Gaida

---

**From:** Hulse, Leslie <Leslie\_Hulse@americanchemistry.com>  
**Sent:** Wednesday, September 26, 2018 2:49 PM  
**To:** Lassiter, Penny  
**Subject:** ACC filed a RFC of the NATA's Use of EO under the Information Quality Act  
**Attachments:** FINAL NATA EO press statement 09-25-18.pdf

Penny,

You may have already heard this, but if not, I wanted to let you know that ACC has filed a Request for Correction of the NATA and its use of the IRIS risk value for EO. We also request that EPA stop using the IRIS risk value for EO in its RTRs and other rulemakings. The attached press release has a link to the filed petition.

Regards,  
Leslie

**Leslie A. Hulse** | American Chemistry Council  
Assistant General Counsel  
[leslie\\_hulse@americanchemistry.com](mailto:leslie_hulse@americanchemistry.com)  
700 2<sup>nd</sup> Street, NE | Washington, DC | 20002  
O: (202) 249-6131  
[www.americanchemistry.com](http://www.americanchemistry.com)

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**Mahgoub, Gaida**

---

**From:** Graham Fitzsimons <gfitzsimons@scainc.com>  
**Sent:** Thursday, September 27, 2018 2:26 PM  
**To:** Lassiter, Penny  
**Cc:** Phil Norwood;Lesley Stobert  
**Subject:** SC&A Category Experience

Hi Penny.

# Ex. 5 Deliberative Process (DP)

## **Ex. 5 Deliberative Process (DP)**

# Ex. 5 Deliberative Process (DP)

Again, thanks Penny for the opportunity to provide this information.  
Please let me or Phil know if you have any questions or would like additional information on the support we can provide on any of the categories.

Best regards,  
Graham

*As of May 1, 2018, I have a new extension and direct-dial phone number (provided below). Please update me in your contact list.*

Graham Fitzsimons  
Senior Vice President  
Office: (919) 484-0222, ext 964  
Direct: (984) 234-3964  
[gfitzsimons@scainc.com](mailto:gfitzsimons@scainc.com)  
[www.scainc.com](http://www.scainc.com)



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**Mahgoub, Gaida**

---

**From:** Parker, Barrett  
**Sent:** Wednesday, October 17, 2018 12:28 PM  
**To:** Lassiter, Penny  
**Subject:** scrubber name change for your consideration

Penny:

## **Ex. 5 Deliberative Process (DP)**

Food for thought,

Barrett

## Mahgoub, Gaida

---

**From:** Terry, Sara  
**Sent:** Wednesday, October 17, 2018 4:05 PM  
**To:** McLamb, Marguerite  
**Cc:** Lassiter, Penny; Cozzie, David; Thompson, Fred  
**Subject:** RE: FYI re EtO discussion on Draft agenda for the OAR Visit - 10/18

Agreed. My understanding is that, now that there is an incoming letter, that certain information will be sent as an email follow up to the phone call (I think the second question about EPA vs ATSDR values falls in this bin), and the rest will go into the letter response, which is on a longer track. So, please keep me in the loop on the outcomes of tomorrow's discussion.

Thanks,  
Sara

---

**From:** McLamb, Marguerite  
**Sent:** Wednesday, October 17, 2018 2:20 PM  
**To:** Terry, Sara <Terry.Sara@epa.gov>  
**Cc:** Lassiter, Penny <Lassiter.Penny@epa.gov>; Cozzie, David <Cozzie.David@epa.gov>; Thompson, Fred <Thompson.Fred@epa.gov>  
**Subject:** FYI re EtO discussion on Draft agenda for the OAR Visit - 10/18

Hi, Sara,  
There is a lunch discussion of EtO on the agenda tomorrow for Bill, Mandy, Alex and David's visit. We should check that the information we provided to OCIR for the responses to Sens. Durbin and Duckworth and may put online is still consistent with the outcomes, if any, of that discussion.  
Best,  
Marguerite

---

**From:** Cozzie, David  
**Sent:** Wednesday, October 17, 2018 8:26 AM  
**To:** OAQPS SPPD GL <OAQPS\_SPPD\_GL@epa.gov>; Conner, Lisa <Conner.Lisa@epa.gov>; Culligan, Kevin <Culligan.Kevin@epa.gov>; Eck, Janet <Eck.Janet@epa.gov>; Joseph, Wanda <joseph.wanda@epa.gov>; McLamb, Marguerite <McLamb.Marguerite@epa.gov>; Srivastava, Ravi <Srivastava.Ravi@epa.gov>; Thompson, Fred <Thompson.Fred@epa.gov>  
**Subject:** FW: Draft agenda for the OAR Visit - 10/18

FYI – Revised agenda to reflect Bill's changed travel plans.

David A. Cozzie  
Acting Director  
Sector Policies and Programs Division  
109 T.W. Alexander Dr.  
RTP, NC 27711  
(919) 541-5356

---

**From:** Lessard, Patrick  
**Sent:** Wednesday, October 17, 2018 8:11 AM

**To:** OAQPS SMT1 <[OAQPS\\_SMT1@epa.gov](mailto:OAQPS_SMT1@epa.gov)>; OAQPS SMT2 <[OAQPS\\_SMT2@epa.gov](mailto:OAQPS_SMT2@epa.gov)>

**Cc:** McKinney, Voronina <[mckinney.voronina@epa.gov](mailto:mckinney.voronina@epa.gov)>

**Subject:** Draft agenda for the OAR Visit - 10/18

Please find attached the latest draft agenda for the OAR (Bill, Mandy, David, and Alex) visit tomorrow. It changed quite a bit yesterday, so I wanted to make sure you have the latest copy. Outlook calendars might not yet reflect all of these changes, but that should catch up today.

Materials for the meetings will be embedded in this agenda. We have not received all materials yet, so please send them as they become available.

Thank you,

Patrick Lessard  
U.S. Environmental Protection Agency  
Office of Air Quality Planning and Standards  
(919) 541-5383

## Mahgoub, Gaida

---

**From:** Caparoso, Jennifer  
**Sent:** Wednesday, October 17, 2018 3:58 PM  
**To:** Lassiter, Penny  
**Cc:** Lavoie, Tegan  
**Subject:** RE: Reminder that we will need to get the revised cover page on the Lanxess survey up to David for Peter tomorrow  
**Attachments:** FINAL MON 114 Letter\_17 Oct 2018.docx

Hi Penny,

Attached is the revised cover letter. The added sentence is highlighted in green.

Thank you,

Jennifer

---

**From:** Lassiter, Penny  
**Sent:** Tuesday, October 16, 2018 4:53 PM  
**To:** Lavoie, Tegan <lavoie.tegan@epa.gov>; Caparoso, Jennifer <Caparoso.Jennifer@epa.gov>  
**Subject:** Reminder that we will need to get the revised cover page on the Lanxess survey up to David for Peter tomorrow

**Mahgoub, Gaida**

---

**From:** Lassiter, Penny  
**Sent:** Thursday, October 18, 2018 10:56 AM  
**To:** Lessard, Patrick  
**Cc:** South, Peter  
**Subject:** RE: Your voicemail

Not same letter. Actually, I think the letter I mentioned is signed off at the SPPD Division Director level. I know what you're talking about. We'll get that one up to you later today - it's the cover letter for the section 114 survey to the MON facility (Lanxess) in North Charleston, SC.

-----Original Message-----

From: Lessard, Patrick  
Sent: Thursday, October 18, 2018 7:27 AM  
To: Lassiter, Penny <Lassiter.Penny@epa.gov>  
Cc: South, Peter <South.Peter@epa.gov>  
Subject: RE: Your voicemail

Thank you Penny.

## Ex. 5 Deliberative Process (DP)

Patrick

-----Original Message-----

From: Lassiter, Penny  
Sent: Wednesday, October 17, 2018 9:49 PM  
To: Lessard, Patrick <Lessard.Patrick@epa.gov>  
Cc: South, Peter <South.Peter@epa.gov>  
Subject: Your voicemail

Patrick,

My apologies for not getting back to you on your voicemail. I saw you called again this evening, but I was on a

## Ex. 5 Deliberative Process (DP)

Sent from my iPhone

## Mahgoub, Gaida

---

**From:** Lassiter, Penny  
**Sent:** Thursday, January 31, 2019 8:12 PM  
**To:** South, Peter  
**Subject:** Fwd: EO Sterilizer Site Visit Letter  
**Attachments:** Site Visit Request 2-12-19\_Penny.docx; ATT00001.htm

Pete,

I've got this on my desk run out on letterhead, but I need to make sure Mike is OK with this visit given it's Sterigenics and ethylene oxide and also, I don't know if anyone on the Coms team has reviewed it. See email below and attachment. Thanks.

Sent from my iPhone

Begin forwarded message:

**From:** "Witt, Jon" <[Witt.Jon@epa.gov](mailto:Witt.Jon@epa.gov)>  
**Date:** January 31, 2019 at 4:36:33 PM EST  
**To:** "Lassiter, Penny" <[Lassiter.Penny@epa.gov](mailto:Lassiter.Penny@epa.gov)>  
**Subject:** EO Sterilizer Site Visit Letter

Hi Penny,

A couple of folks in OAQPS (and RTI) are planning a site visit to an EO sterilizer in Charlotte on February 12, 2019. I left a site visit letter that Steve and I reviewed on your desk for your signature (also attached). This is the standard form letter that we typically use for site visits. Please let me know if you have any questions.

Thanks so much,  
Jonathan

---

**Jonathan W. Witt, EI**  
Environmental Engineer  
Office of Air Quality Planning and Standards  
EPA|OAR|OAQPS|SPPD|FIG  
109 T.W. Alexander Dr. | Mail Drop: E143-05 | Durham, NC 27703  
+1.919.541.5645 (work) | +1.919.541.7885 (fax)

## Lavenburg, Andrew

---

**From:** Lassiter, Penny  
**Sent:** Monday, February 11, 2019 9:08 AM  
**To:** Perry, Nancy  
**Cc:** Brown, Annette; Cozzie, David; South, Peter  
**Subject:** STRONGER Air Guidelines

Nancy,

We have a conflict with this meeting. Peter has scheduled a meeting on ethylene oxide at this same time this morning. This one will need to be moved. Thanks.

-----  
**Subject:** STRONGER Air Guidelines  
**Location:** RTP-OAQPS-D210A-SPPD-IO-only/RTP-OAQPS-BLDG-D/Restricted; Call in number Ex. 6 Personal Privacy (PP)  
Ex. 6 Personal Privacy (PP)  
**Start:** Mon 2/11/2019 10:00 AM  
**End:** Mon 2/11/2019 11:00 AM  
**Recurrence:** (none)  
**Meeting Status:** Meeting organizer  
**Organizer:** Lassiter, Penny  
**Required Attendees:** Marsh, Karen; Fruh, Steve; Cozzie, David; Hambrick, Amy

Background: STRONGER is the State Review of Oil and Natural Gas Environmental Regulations. This is a group comprised of representatives from states, NGOs, and industry. I hold one of 2 EPA non-voting positions on the executive board. STRONGER recently voted to update the Air Quality Guidelines that were initially developed in 2014 with an emphasis on VOC and HAP emissions. The proposed updates are intended to expand that scope to include methane emissions from upstream oil and gas operations. These guidelines are intended to guide states in accessing and improving their regulatory programs for waste management, abandoned sites, naturally occurring radioactive materials, storm water management, hydraulic fracturing, air quality, and reused and recycled fluids. The guidelines set out elements of an effective program using "should" rather than mandating specific requirements. Therefore, states are able to apply specific criteria based on their particular needs.

POC: Karen Marsh x1-1065

## Mahgoub, Gaida

---

**From:** Davis, Alison  
**Sent:** Friday, November 9, 2018 9:53 AM  
**To:** Tsirigotis, Peter  
**Subject:** FW: Following up on my voicemail

FYI. Just so you know I called/sent.

---

**From:** Davis, Alison  
**Sent:** Friday, November 09, 2018 9:40 AM  
**To:** Rakosnik, Delaney <rakosnik.delaney@epa.gov>  
**Subject:** Following up on my voicemail

Hi Delaney,

Here is the list of names for the OAQPS discussion with Bill in advance of the 4 p.m. call with R5 today. Please call if you have any questions.

Mike Koerber  
Richard Wayland  
Erika Sasser  
Lewis Weinstock  
Deirdre Murphy  
Amy Vasu  
Alison Davis

Please cc: Peter T. and Kelly Rimer (she is out)

Thanks so much!

-Alison

---

Alison Davis  
Acting Director  
Policy Analysis & Communications Staff  
US EPA, Office of Air Quality Planning & Standards  
Research Triangle Park, NC 27711  
Desk: 919-541-7587  
Mobile: 919-624-0872

## Mahgoub, Gaida

---

**From:** Davis, Alison  
**Sent:** Friday, November 9, 2018 9:40 AM  
**To:** Rakosnik, Delaney  
**Subject:** Following up on my voicemail

Hi Delaney,

Here is the list of names for the OAQPS discussion with Bill in advance of the 4 p.m. call with R5 today. Please call if you have any questions.

Mike Koerber

Richard Wayland

Erika Sasser

Lewis Weinstock

Deirdre Murphy

Amy Vasu

Alison Davis

Please cc: Peter T. and Kelly Rimer (she is out)

Thanks so much!

-Alison

-----  
Alison Davis

Acting Director

Policy Analysis & Communications Staff

US EPA, Office of Air Quality Planning & Standards

Research Triangle Park, NC 27711

Desk: 919-541-7587

Mobile: 919-624-0872

## **Mahgoub, Gaida**

---

**From:** Noonan, Jenny  
**Sent:** Sunday, November 11, 2018 3:59 PM  
**To:** Tsirigotis, Peter  
**Cc:** Davis, Alison; Koerber, Mike  
**Subject:** FYI -- elevation

Peter –

Alison looped Nancy Grantham in and Nancy has reached out to the head of OEI. They are calling me now. Will keep you posted.

Thanks,  
Jenny

## Mahgoub, Gaida

---

**From:** Woods, Clint  
**Sent:** Saturday, February 16, 2019 6:27 AM  
**To:** Wehrum, Bill  
**Cc:** Harlow, David; Lewis, Josh; Tsirigotis, Peter; Koerber, Mike; Davis, Alison; DeLuca, Isabel; Konkus, John; Jackson, Ryan  
**Subject:** Re: IL EPA

[www.chicagotribune.com/news/local/breaking/ct-met-pritzker-sterigenics-shutdown-willowbrook-20190215-story,amp.html](http://www.chicagotribune.com/news/local/breaking/ct-met-pritzker-sterigenics-shutdown-willowbrook-20190215-story,amp.html)

On Feb 15, 2019, at 7:15 PM, Wehrum, Bill <[Wehrum.Bill@epa.gov](mailto:Wehrum.Bill@epa.gov)> wrote:

FYI

---

Bill Wehrum  
Assistant Administrator  
Office of Air and Radiation  
U.S. Environmental Protection Agency  
(202) 564-7404

Begin forwarded message:

**From:** "Macnabb, Philip" <[PMacnabb@sterigenics.com](mailto:PMacnabb@sterigenics.com)>  
**Date:** February 15, 2019 at 7:12:16 PM EST  
**To:** "[Wehrum.Bill@epa.gov](mailto:Wehrum.Bill@epa.gov)" <[Wehrum.Bill@epa.gov](mailto:Wehrum.Bill@epa.gov)>  
**Cc:** "[tcr@vnf.com](mailto:tcr@vnf.com)" <[tcr@vnf.com](mailto:tcr@vnf.com)>  
**Subject:** IL EPA

Bill

I wanted to make you aware that tonight at 5pm we received a "seal order" from IL EPA to stop using EO due to public health crisis. We will stop processing until we can get in front of a judge.

Feel free to call my cell at (919) Ex. 6 Personal Privacy (PP) if you would like further details.

Sent from my iPhone

This e-mail and any files transmitted with it may contain privileged and/or confidential information. If you believe this e-mail or any of its attachments were not intended for you, you must not use, distribute, forward, print or copy this e-mail or any attached files. If you have received this e-mail in error, please notify the sender by reply e-mail and then immediately delete the email and all attachments.

## **Mahgoub, Gaida**

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**From:** Tsirigotis, Peter  
**Sent:** Tuesday, July 24, 2018 2:38 PM  
**To:** Wehrum, Bill  
**Subject:** Accepted: Pre-brief for Ethylene Oxide Emissions Follow-up

## Mahgoub, Gaida

---

**From:** Koerber, Mike  
**Sent:** Wednesday, July 25, 2018 7:49 PM  
**To:** Tsirigotis, Peter  
**Subject:** Fwd: draft  
**Attachments:** Suggested key points to cover with RAs DRAFT - revised.ad.docx; ATT00001.htm

Peter - Thanks for the voicemail. We already have talking points in motion- see below and attached. Let's talk in the morning about this.

Sent from my iPhone

Begin forwarded message:

**From:** "Davis, Alison" <[Davis.Alison@epa.gov](mailto:Davis.Alison@epa.gov)>  
**Date:** July 25, 2018 at 5:58:57 PM EDT  
**To:** "Koerber, Mike" <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)>, "Jones, Rhea" <[Jones.Rhea@epa.gov](mailto:Jones.Rhea@epa.gov)>, "Wayland, Richard" <[Wayland.Richard@epa.gov](mailto:Wayland.Richard@epa.gov)>  
**Cc:** "Sasser, Erika" <[Sasser.Erika@epa.gov](mailto:Sasser.Erika@epa.gov)>, "Cozzie, David" <[Cozzie.David@epa.gov](mailto:Cozzie.David@epa.gov)>  
**Subject:** RE: draft

Some edits and a question from me. Thanks.

---

**From:** Koerber, Mike  
**Sent:** Wednesday, July 25, 2018 5:42 PM  
**To:** Jones, Rhea <[Jones.Rhea@epa.gov](mailto:Jones.Rhea@epa.gov)>; Davis, Alison <[Davis.Alison@epa.gov](mailto:Davis.Alison@epa.gov)>; Wayland, Richard <[Wayland.Richard@epa.gov](mailto:Wayland.Richard@epa.gov)>  
**Cc:** Sasser, Erika <[Sasser.Erika@epa.gov](mailto:Sasser.Erika@epa.gov)>; Cozzie, David <[Cozzie.David@epa.gov](mailto:Cozzie.David@epa.gov)>  
**Subject:** RE: draft

Thanks, Rhea. Your changes look fine to me. I forgot to include something on messaging and next steps, so I added them into the attachment. Please let me know if there are any further comments.

Mike

---

**From:** Jones, Rhea  
**Sent:** Wednesday, July 25, 2018 4:51 PM  
**To:** Koerber, Mike <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)>  
**Cc:** Sasser, Erika <[Sasser.Erika@epa.gov](mailto:Sasser.Erika@epa.gov)>; Wayland, Robertj <[Wayland.Robertj@epa.gov](mailto:Wayland.Robertj@epa.gov)>; Cozzie, David <[Cozzie.David@epa.gov](mailto:Cozzie.David@epa.gov)>  
**Subject:** FW: draft

Hi Mike,

I was thinking about this as well. This looks good to us, and I've made a couple of edits/additions to your file.

Thanks!

---

**From:** Sasser, Erika  
**Sent:** Wednesday, July 25, 2018 4:09 PM  
**To:** Jones, Rhea <[Jones.Rhea@epa.gov](mailto:Jones.Rhea@epa.gov)>  
**Subject:** FW: draft

---

**From:** Koerber, Mike  
**Sent:** Wednesday, July 25, 2018 3:00 PM  
**To:** Sasser, Erika <[Sasser.Erika@epa.gov](mailto:Sasser.Erika@epa.gov)>; Wayland, Richard <[Wayland.Richard@epa.gov](mailto:Wayland.Richard@epa.gov)>; Cozzie, David <[Cozzie.David@epa.gov](mailto:Cozzie.David@epa.gov)>  
**Subject:** draft

Erika, Chet, David – This wasn't asked for, but I thought it would be helpful if we put down the messages we think need to be communicated tomorrow. Take a look at the attachment and edit as necessary.  
Thanks.

Mike

## **Mahgoub, Gaida**

---

**From:** Koerber, Mike  
**Sent:** Thursday, July 26, 2018 8:04 AM  
**To:** Woods, Clint;Lewis, Josh;Tsirigotis, Peter  
**Cc:** Davis, Alison;Sasser, Erika;Wayland, Richard;Cozzie, David  
**Subject:** Draft talking points  
**Attachments:** Suggested key points to cover with RAs july 26.docx

**Categories:** Record Saved - Private

Clint: Here are draft talking points to use for today's call with the RAs. Let me know what you think. My understanding is that Bill intends to kick-off the call and then hand it to OAQPS. Thanks.

Mike

## **Mahgoub, Gaida**

---

**From:** Tsirigotis, Peter  
**Sent:** Friday, September 7, 2018 7:59 PM  
**To:** Koerber, Mike  
**Subject:** Talk tonight or tomorrow?

## **Mahgoub, Gaida**

---

**From:** Tsirigotis, Peter  
**Sent:** Friday, September 7, 2018 8:40 PM  
**To:** Wehrum, Bill  
**Subject:** Accepted: Ethylene Oxide Discussion

## Mahgoub, Gaida

---

**From:** Wehrum, Bill  
**Sent:** Friday, October 26, 2018 6:56 PM  
**To:** Gunasekara, Mandy; Woods, Clint; Lewis, Josh; Tsirigotis, Peter; Davis, Alison; Rimer, Kelly  
**Subject:** Fwd: Letter re: EtO emissions in Lake County  
**Attachments:** 181026- AGO Letter to USEPA Re Lake County.pdf; ATT00001.htm  
  
**Categories:** Record Saved - Private

FYI

---

Bill Wehrum  
Assistant Administrator  
Office of Air and Radiation  
U.S. Environmental Protection Agency  
(202) 564-7404

Begin forwarded message:

**From:** "Wallace, Elizabeth" <EWallace@atg.state.il.us>  
**Date:** October 26, 2018 at 6:42:49 PM EDT  
**To:** "'wehrum.william@epa.gov'" <wehrum.william@epa.gov>, "Nam, Ed" <nam.ed@epa.gov>  
**Cc:** "Dunn, Matthew" <MDunn@atg.state.il.us>  
**Subject:** Letter re: EtO emissions in Lake County

Hello,

Please see attached.

Elizabeth Wallace, Chief  
Environmental Bureau / Chicago  
Office of the Illinois Attorney General  
69 W. Washington St., 18<sup>th</sup> Flr.  
Chicago, IL 60602  
(312)814-5396  
(312)814-2347 (fax)  
[ewallace@atg.state.il.us](mailto:ewallace@atg.state.il.us)

## Mahgoub, Gaida

---

**From:** Tsirigotis, Peter  
**Sent:** Wednesday, October 17, 2018 7:42 AM  
**To:** Koerber, Mike  
**Subject:** Fwd: Sterigenics US LLC

Begin forwarded message:

**From:** "Woods, Clint" <[woods.clint@epa.gov](mailto:woods.clint@epa.gov)>  
**Date:** October 17, 2018 at 7:23:49 AM EDT  
**To:** "Wayland, Richard" <[Wayland.Richard@epa.gov](mailto:Wayland.Richard@epa.gov)>  
**Cc:** "Tsirigotis, Peter" <[Tsirigotis.Peter@epa.gov](mailto:Tsirigotis.Peter@epa.gov)>  
**Subject:** Re: Sterigenics US LLC

Chet,

Spoke to Alec a 2nd time yesterday - Key takeaways:

1. Less detail in a one pager on monitoring/plans is fine.
2. We'll look to schedule a follow up call in the next week or so, which will only include IL EPA (and primarily their technical team).

On Oct 15, 2018, at 8:06 AM, Wayland, Richard <[Wayland.Richard@epa.gov](mailto:Wayland.Richard@epa.gov)> wrote:

Thanks Clint. I think that would be very helpful.

Thanks  
Chet

Richard A. "Chet" Wayland  
Sent from my iPhone

On Oct 15, 2018, at 8:03 AM, Woods, Clint <[woods.clint@epa.gov](mailto:woods.clint@epa.gov)> wrote:

Chet,

Please excuse my delay - If you don't mind, I'd like to check in with Alec Messina who runs IL EPA today to make sure I understand their interest and we can figure out logistics for a discussion on monitoring/modeling plans.

On Oct 12, 2018, at 9:33 PM, Wayland, Richard  
<[Wayland.Richard@epa.gov](mailto:Wayland.Richard@epa.gov)> wrote:

Clint,

I took a call from the gentleman below and he followed up with the email below about having a call with us on

what modeling and monitoring EPA was planning for the Willowbrook facility. I checked with Peter and he agreed I should check in with you. Do you have some thoughts on how you'd like us to follow up? We can of course let him know what we are planning to do but given the litigation issues I wanted to touch base with you first. Maybe we can chat early next week.

Thanks  
Chet

Richard A. "Chet" Wayland  
Sent from my iPhone

Begin forwarded message:

**From:** "Kim, John J."  
<[John.J.Kim@Illinois.gov](mailto:John.J.Kim@Illinois.gov)>  
**Date:** October 11, 2018 at 2:25:03 PM  
EDT  
**To:** "[wayland.richard@epa.gov](mailto:wayland.richard@epa.gov)"  
<[wayland.richard@epa.gov](mailto:wayland.richard@epa.gov)>  
**Subject:** Sterigenics US LLC

Thank you for taking time to speak with me on the phone today. To recap, my request was for a phone call with you or your staff so that interested government representatives in Illinois (from the Illinois EPA and the Illinois Attorney General's Office) can better understand what the scope and parameters of modeling to be done based on recent stack test results from the Sterigenics facility in Willowbrook, Illinois.

We are interested in learning about what goals are being pursued, estimates of timelines, relation of modeling to ambient air modeling, and related subjects. This would help greatly with the State's efforts to effectively respond to the conditions at the Sterigenics facility in an appropriate manner.

I look forward to hearing from you.

John K.

-----  
---  
  
John J. Kim  
Chief Legal Counsel  
Illinois Environmental Protection  
Agency  
Division of Legal Counsel  
1021 North Grand Avenue, East  
P.O. Box 19276  
Springfield, IL 62794-9276  
217.785.8628  
217.782.9807 (Fax)  
E-mail: [john.j.kim@illinois.gov](mailto:john.j.kim@illinois.gov)

State of Illinois - CONFIDENTIALITY  
NOTICE: The information contained in  
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privilege, attorney work product  
privilege, or any other exemption from  
disclosure.



OFFICE OF THE ATTORNEY GENERAL  
STATE OF ILLINOIS

Lisa Madigan  
ATTORNEY GENERAL

October 26, 2018

SENT VIA EMAIL

Mr. William L. Wehrum  
Assistant Administrator  
Office of Air and Radiation  
Environmental Protection Agency  
1200 Pennsylvania Avenue, N.W.  
6101A  
Washington, D.C. 20460

Dear Mr. Wehrum:

We are writing to ask that U.S. EPA take critical additional steps regarding ethylene oxide emissions ("EtO") in Illinois based on our review of the 2014 NATA for Illinois. As you know, the 2014 NATA shows two areas with a cancer risk over 100 in 1,000,000 – one area is in and around Willowbrook, DuPage County, and the second is in and around Waukegan, Lake County. The Willowbrook area is linked to EtO emissions from Sterigenics and has been the subject of ambient air testing and an ATSDR report. On the other hand, we are not aware of air testing by U.S. EPA or analysis by ATSDR of the emissions in the Lake County area.

The higher cancer risk area in Lake County appears to be related to EtO emissions from Medline Industries, which reported EtO emissions of 3,057.6 pounds as set forth in the 2014 National Emission Inventory ("2014 NEI") for EtO. However, Vantage Specialties, located just 3.2 miles north of Medline, reported emitting 6,412 pounds of EtO as set forth on its 2014 Toxics Release Inventory Form R and is not included in the 2014 NATA.

We ask that U.S. EPA update the 2014 NATA and review what changes to the 2014 NATA area map would occur if the EtO emissions from Vantage Specialties had been included. Adding the 2014 EtO emissions from Vantage to the Medline emissions more than doubles the amount of EtO released into those communities. Additionally, due to the amount of EtO emitted from these two facilities in such close proximity to each other, we ask that U.S. EPA perform ambient air

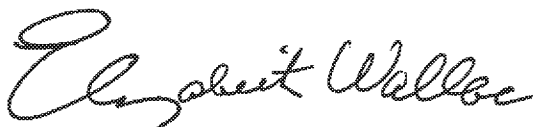
Mr. William Wehrum  
October 26, 2018  
Page 2

monitoring in those areas also. Once U.S. EPA completes the air testing, we ask that you consider having ATSDR analyze the impact to the community from EtO emissions.

Lastly, once U.S. EPA updates the 2014 NATA to include the Vantage data, it is imperative that U.S. EPA provide relevant information to the community immediately to assist the community in understanding the current knowledge on this matter.

I would appreciate hearing back from you as soon as possible on this important issue. Thank you very much.

Very truly yours,

A handwritten signature in black ink, appearing to read "Elizabeth Wallace". The signature is fluid and cursive, with the first name "Elizabeth" written in a larger, more prominent script than the last name "Wallace".

Elizabeth Wallace, Chief  
Environmental Bureau North  
Assistant Attorney General  
Office of the Illinois Attorney General  
69 West Washington Street, Suite 1800  
Chicago, IL 60602  
(312) 814-5396  
ewallace@atg.state.il.us

Cc: Senator Durbin  
Senator Duckworth  
Mr. Ed Nam, U.S. EPA, Region V

## **Mahgoub, Gaida**

---

**From:** Tsirigotis, Peter  
**Sent:** Thursday, November 8, 2018 7:36 PM  
**To:** Cozzie, David  
**Subject:** Question

How is the ethylene RTR going? Is there a package?

**From:** Rakosnik, Delaney on behalf of Wehrum, Bill  
**To:** Harlow, David; Woods, Clint; Gunasekara, Mandy; Lewis, Josh; Tsirigotis, Peter; Koerber, Mike; Sasser, Erika; Wayland, Richard; Langdon, Robin; Smith, Darcie; Shelow, David; Palma, Ted; Truesdell, Raymond; Riha, Kristin; Jones, Rhea; Bremer, Kristen; Davis, Alison; Cozzie, David; Caparoso, Jennifer; Servidio, Cosmo; Fernandez, Daniel; Arnold, David; Glenn, Trey; Banister, Beverly; Mitchell, Ken; Stepp, Cathy; Nam, Ed; Payne, James; Thiede, Kurt; Furey, Eileen; Idsal, Anne; Stenger, Wren; Gray, David; Verhalen, Frances  
**Subject:** Ethylene Oxide Emissions and Identified Potential Health Risks  
**Attachments:** Wehrum Meeting Request EtO w RAs on Tuesday 7/17 at 10 am ET: location EPA-RTP.msg

TO: David Harlow, Clint Woods, Mandy Gunasekara, Josh Lewis, Peter Tsirigotis, Mike Koerber, Erika Sasser, Richard Wayland, Robin Langdon, Darcie Smith, David Shelow, Ted Palma, Raymond Truesdell, Kristin Riha, Rhea Jones, Kristin Bremer, Alison Davis, David Cozzie, Jennifer Caparoso, Cosmo Servidio, Christina Fernandez, David Arnold, Trey Glenn, Beverly Banister, Ken Mitchell, Cathy Stepp, Ed Nam, James Payne, Kurt Thiede, Eileen Furey, Anne Idsal, Wren Stenger, David Gray, Frances Verhalen

PURPOSE: To discuss potential health risks identified from ethylene oxide emissions for areas in Regions 3, 4, 5 and 6.

Message

---

**From:** McKinney, Voronina [mckinney.voronina@epa.gov]  
**Sent:** 7/11/2018 8:42:23 PM  
**To:** Rakosnik, Delaney [rakosnik.delaney@epa.gov]  
**CC:** Atkinson, Emily [Atkinson.Emily@epa.gov]; Lewis, Josh [Lewis.Josh@epa.gov]; South, Peter [South.Peter@epa.gov]; Mozingo, Kristal [Mozingo.Kristal@epa.gov]  
**Subject:** Wehrum Meeting Request: EtO w/ RAs on Tuesday, 7/17 at 10 am ET; location: EPA-RTP  
**Attachments:** OAR AA Meeting Request EtO with RAs 07\_17\_18.docx

Hi Delaney,

Wehrum Meeting Request: Please schedule the EtO with RAs during Bill and the OAR team visit to EPA-RTP on Tuesday, July 17th at 10:00 am ET. Meeting request is attached to this email. Please contact me with any questions or concerns.

I appreciate you,

Nina

Voronina McKinney  
Program Specialist  
U.S. Environmental Protection Agency  
OAR|Office of Air Quality Planning and Standards|Immediate Office  
(919) 541-5616

UNC-Chapel Hill University & Duke University Alumni| US Navy Veteran

[ SEQ CHAPTER \h \r 1]OAR Meeting Request Form  
For Bill Wehrum

**Date of this Request:** 07/11/2018

**Scheduling Point of Contact:** Nina McKinney 919-541-5616

**Technical Point of Contact:** Erika Sasser 919-541-3889

**Subject:** Ethylene Oxide Emissions and Identified Potential Health Risks

**Purpose:** To discuss potential health risks identified from ethylene oxide emissions for areas in Regions 3, 4, 5 and 6.

- Next ADP Milestone:
- If applicable, due date to: OP \_\_/\_\_/\_\_ ( days review); OMB: \_\_/\_\_/\_\_ (days review);
- Legal deadline: (specify court-ordered, settle agreement, court promise, etc.) due date \_\_/\_\_/\_\_;
- Other firm deadline:

**First possible date for meeting:** 07/17/2018 (10:00 am ET would be preferred time)

**Last possible date for meeting:** 07/17/2018

**Duration:** 45 minutes

**Requested Audio / Video** (*Mark with "X" if requested*)

\_\_\_\_\_ **Video Location(s):**

*List video locations needed (e.g., RTP, DC, Regions)– HQ will set up a bridge if needed*

\_\_\_\_\_ **HQ Conference Line:**

*If requested, HQ staff will provide in meeting invite*

**Invitees (please list by Office and in Outlook format, e.g. *Last, First*):**

<u>Office/Org</u>	<u>Name (<i>Last, First</i>)</u>
OAR	Harlow, David; Woods, Clint; Gunasekara, Mandy; Lewis, Josh
OAQPS	Tsirigotis, Peter; Koerber, Mike; Sasser, Erika; Wayland, Richard; Langdon, Robin; Smith, Darcie; Shelow, David; Palma, Ted; Truesdell, Raymond; Riha, Kristin; Jones, Rhea; Bremer, Kristen; Davis, Alison; Cozzie, David; Caparoso, Jennifer
Region 3	Servidio, Cosmo; Fernandez, Cristina; Arnold, David
Region 4	Glenn, Trey; Banister, Beverly; Mitchell, Ken
Region 5	Stepp, Cathy; Nam, Ed; Payne, James; Thiede, Kurt; Furey, Eileen
Region 6	Idsal, Anne; Stenger, Wren; Gray, David; Verhalen, Frances

**From:** [Woods, Clint](#)  
**To:** [DeLuca, Isabel](#)  
**Cc:** [Wehrum, Bill](#); [Millet, John](#)  
**Subject:** Re: In about-face, Gov. Bruce Rauner calls for Sterigenics shutdown after weeks of downplaying cancer risks - Chicago Tribune  
**Date:** Wednesday, October 3, 2018 5:35:24 AM

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Thanks. Updated Willowbrook site is available here, and Kelly R will be taking lead on any additional inquiries from IL officials:

<https://www.epa.gov/il/sterigenics-willowbrook-facility>

On Oct 3, 2018, at 8:32 AM, DeLuca, Isabel <[DeLuca.Isabel@epa.gov](mailto:DeLuca.Isabel@epa.gov)> wrote:

In case you haven't seen this:

<http://www.chicagotribune.com/news/local/breaking/ct-met-bruce-rauner-sterigenics-shutdown-20181002-story.html>

## **In about-face, Gov. Bruce Rauner calls for Sterigenics shutdown after weeks of downplaying cancer risks**

[Michael Hawthorne](#)



After spending the past month downplaying [cancer](#) risks from toxic air pollution in west suburban Willowbrook, Gov. Bruce Rauner on Tuesday joined a chorus of elected officials calling for the shutdown of a Sterigenics International facility co-owned by his former private equity firm.

Fellow Republicans from DuPage County have been clamoring for Rauner to take more aggressive action against the company, which for more than three decades has used highly potent [ethylene oxide gas](#) to sterilize medical instruments, pharmaceutical drugs and food near densely populated neighborhoods and several schools.

As recently as Friday, the most the Republican governor would say about

Sterigenics was that he had instructed the Illinois Environmental Protection Agency to launch an investigation. But Rauner changed course after the weekend, ordered his staff to refer the case to Illinois Attorney General Lisa Madigan, the state's chief lawyer, then urged the Democrat to seek a court order that would close the Willowbrook facility until a separate federal investigation "assures the community that resumed operations would not present an elevated health risk."

Rauner's sudden reversal comes as local politicians, many of whom like the governor are on the Nov. 6 ballot, face a fury of complaints about a federal report that revealed unusually high cancer risks from ethylene oxide pollution in traditionally Republican communities near Sterigenics. Citizen groups that quickly organized against the company garnered even more attention when Burr Ridge resident Andrea Thome and her husband, former Chicago White Sox slugger Jim Thome, added their voices to the anti-Sterigenics movement.

"There is a level of anger in the community that I've never seen before," said longtime state Rep. Jim Durkin of Darien, the House Republican leader and one of several DuPage County officials calling for Sterigenics to be shut down. "This area is populated by young families who are moving here from the city. I know people within a half-mile of the facility who feel they aren't getting any answers and they don't feel anybody is standing up on their behalf."

The Tribune previously reported that quick action is unlikely for a variety of reasons, including steps the Rauner administration took before and after the Willowbrook cancer report was released to the public in late August.

Nearly two months earlier, the Illinois EPA responded to the then-secret report by quietly giving Sterigenics a permit to voluntarily install new pollution-control equipment, making it more difficult for authorities to pursue legal action against the company unless it can be proved that the fix has failed to eliminate health risks from ethylene oxide pollution.

Rauner appointees later refused to provide Madigan's office with key documents about the Willowbrook facility, required the attorney general's staff to request the records under the Freedom of Information Act and delayed providing the information until after the Tribune inquired about the

dispute on Sept. 20. Even now, Madigan said, the state can't make an effective case against Sterigenics without more air quality monitoring in surrounding neighborhoods, expert analysis of the results and other information that only the state or federal EPA can provide.

"We are prepared to move forward in court and have told IEPA what evidence is necessary to shut the site down," Madigan said. "IEPA has not provided any evidence, but we will immediately evaluate any information the agency provides."

With Election Day just a few weeks away, locally elected officials have repeatedly urged state and federal regulators to reassure the public they are safe. Rauner, along with top Trump administration officials at the U.S. Environmental Protection Agency, have stressed that there is no evidence Sterigenics poses the type of immediate threats seen in some work settings. But the company has been releasing ethylene oxide into surrounding communities since the early 1980s, federal records show, and the health risks involve diseases that can take years to develop, including breast cancer, leukemia and lymphoma.

Based on air samples collected in May, an arm of the federal Centers for Disease Control and Prevention determined the cancer risks from breathing ethylene oxide pollution in southeast DuPage communities could be orders of magnitude higher than initially estimated: up to 6,400 per million, or more than six cases of cancer for every 1,000 people. The U.S. EPA generally targets polluters when local cancer risks exceed 100 in a million.

The pre-election political stakes are high enough that the Trump administration weighed in on the issue last week, dispatching a presidential appointee in charge of the EPA's air division to promise the agency will conduct the type of neighborhood air monitoring that Madigan and others have been calling for during the past month.

Sterigenics said a controlled test of emissions, conducted in late September by consultants hired by the company, failed to detect any ethylene oxide leaving its pair of buildings in Willowbrook.

"We are committed to doing the right thing by our community but closing facilities that emit limited, regulated (ethylene oxide) emissions is not the right answer," the company said in a statement, calling Rauner's latest

reaction “ill-considered.” “If necessary, we will take all appropriate actions to protect the hospitals and patients that depend on our facility.”

Rauner’s ties to the company date to 2011, when a private equity firm he co-founded bought Sterigenics for \$675 million and quickly expanded its operations. The governor’s most recent state ethics statement, filed in May, shows he retains an interest in the fund used to buy the sterilization company, which in 2015 sold a majority stake to another private equity firm.

On Friday morning, Rauner told radio station WBEZ he no longer has a stake in Sterigenics. Spokespeople for his campaign and government office later told the Tribune that Rauner sold his interest as part of the 2015 deal but have not produced documents showing the transaction took place.

“We will get the truth about what has been emitted so far,” Rauner told the radio station, “and what needs to change in the future.”

[mhawthorne@chicagotribune.com](mailto:mhawthorne@chicagotribune.com)

Twitter [@scribeguy](#)

## **MORE COVERAGE**

[After weeks of public outrage about Sterigenics, Trump EPA to test air in surrounding neighborhoods »](#)

[Rauner EPA withholds Sterigenics records from attorney general until local Republicans intervene »](#)

[High cancer risk in southeast DuPage County linked to company co-owned by Rauner’s former firm »](#)

-----

**Jeff Kelley**

Director, Office of External Communications

U.S. EPA Region 5

ph: 312-353-1159

**From:** [Woods, Clint](#)  
**To:** [DeLuca, Isabel](#)  
**Cc:** [Wehrum, Bill](#); [Millett, John](#)  
**Subject:** Re: NATA comms  
**Date:** Tuesday, August 21, 2018 3:48:35 PM

---

Isabel,

I will have substantial changes to R5 desk statement, and will send a copy back to you and John. Thanks!

Clint

On Aug 21, 2018, at 6:46 PM, DeLuca, Isabel <[DeLuca.Isabel@epa.gov](mailto:DeLuca.Isabel@epa.gov)> wrote:

Hi Bill and Clint,

The R5 desk statement on Sterigenics is attached for your review. I've also attached the HQ desk statement, NATA fact sheet, and EtO fact sheets – OPA sent these to the regions this afternoon.

Clint— if the R5 desk statement looks ok to you, can you please forward to John Konkus (and cc me so I know it's final too)? John wants to make sure this has cleared OAR IO before he approves.

The plan is to post NATA tomorrow at 2 pm.

Thanks,  
Isabel

**Isabel DeLuca**  
Office of Air and Radiation, US EPA  
(202) 343-9247

<20180821-Sterigenics\_desk\_statement.docx>

<NATA desk statement 8.21.18.docx>

<Ethylene Oxide Fact Sheet.Final.8.21.18.pdf>

<2014 NATA Overview Fact Sheet..pdf>

**From:** [Woods, Clint](#)  
**To:** [Wehrum, Bill](#); [Gunasekara, Mandy](#)  
**Subject:** FW: Wheeler9252018.pdf  
**Date:** Wednesday, September 26, 2018 2:21:52 PM  
**Attachments:** [Wheeler9252018.pdf](#)  
[ATT00001.txt](#)

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Just spoke to Alec Messina who runs IL EPA. He understands the limits of ambient monitoring. Offered assistance if IL EPA wanted to pursue, but we should be singing off the same sheet of music Friday regarding the need to focus on stack testing/modeling 1st.

-----Original Message-----

From: Lyons, Troy  
Sent: Wednesday, September 26, 2018 5:17 PM  
To: Jackson, Ryan <[jackson.ryan@epa.gov](mailto:jackson.ryan@epa.gov)>; Wehrum, Bill <[Wehrum.Bill@epa.gov](mailto:Wehrum.Bill@epa.gov)>; Woods, Clint <[woods.clint@epa.gov](mailto:woods.clint@epa.gov)>; Gunasekara, Mandy <[Gunasekara.Mandy@epa.gov](mailto:Gunasekara.Mandy@epa.gov)>; Konkus, John <[konkus.john@epa.gov](mailto:konkus.john@epa.gov)>; Harlow, David <[harlow.david@epa.gov](mailto:harlow.david@epa.gov)>  
Cc: Cory, Preston (Katherine) <[Cory.Preston@epa.gov](mailto:Cory.Preston@epa.gov)>; Ringel, Aaron <[ringel.aaron@epa.gov](mailto:ringel.aaron@epa.gov)>; Palich, Christian <[palich.christian@epa.gov](mailto:palich.christian@epa.gov)>; Frye, Tony (Robert) <[frye.robert@epa.gov](mailto:frye.robert@epa.gov)>; Rodrick, Christian <[rodrick.christian@epa.gov](mailto:rodrick.christian@epa.gov)>  
Subject: Wheeler9252018.pdf

FYI—We just received this letter from the state

**From:** Wehrum, Bill  
**To:** Woods, Clint  
**Subject:** Re: R5 Follow up  
**Date:** Tuesday, September 11, 2018 4:35:08 PM

---

Thanks Clint. Let's plan to catch up tomorrow at some point.

Separately, are you up to speed on the SSM issues that will be discussed in tomorrow's briefing? If so, are you comfortable?

---

Bill Wehrum  
Assistant Administrator  
Office of Air and Radiation  
U.S. Environmental Protection Agency  
(202) 564-7404

> On Sep 11, 2018, at 7:29 PM, Woods, Clint <woods.clint@epa.gov> wrote:

>

> Bill,

>

> I'll be in TX tmrw for HEI, but 2 follow up items from R5 call:

## **Ex. 5 Deliberative Process (DP)**

>

> Thanks!

>

> Clint

**From:** [Bremer, Kristen](#)  
**To:** [Tsirigotis, Peter](#)  
**Cc:** [Koerber, Mike](#); [Noonan, Jenny](#); [Davis, Alison](#)  
**Subject:** Draft Action Plan  
**Date:** Monday, March 4, 2019 10:36:22 AM  
**Attachments:** [EtO Action Plan.docx](#)

---

Hi Peter,

I've attached a copy of the draft action plan that Jenny discussed with you last week. This plan includes input from Mike, Alison, Jenny and me. If you have any questions, please don't hesitate to ask. Thanks!

---

Kristen Bremer  
Policy Analysis & Communications  
U.S. EPA, Office of Air Quality Planning & Standards  
Email: [bremer.kristen@epa.gov](mailto:bremer.kristen@epa.gov)  
Phone: 919.541.9424  
Cell: 919.321.7652

**From:** Ashley, Jackie  
**To:** Weinstock, Lewis; Davis, Alison  
**Cc:** Koerber, Mike; Noonan, Jenny  
**Subject:** RE: EtO updates for the Monday ADD call  
**Date:** Monday, February 25, 2019 10:02:28 AM  
**Attachments:** ETO legislation TPs - 25Feb19.docx

---

Pasted below are some talking points on legislation. The attached document includes the same TPs – along with the likely text of each bill. Note that the bills introduced on 2/12/19 for this Congress are not posted yet on Congress.gov, so the word document includes the text from the bills in the last congress. We are pretty sure they are identical, but please only use this for reference and do not distribute this document broadly.

-Jackie

#### Talking points on EtO legislation

## Ex. 5 Deliberative Process (DP)

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Jackie Ashley - US EPA - Office of Air Quality Planning and Standards - 919-541-7664 – ashley.jackie@epa.gov  
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**From:** Weinstock, Lewis

**Sent:** Sunday, February 24, 2019 12:26 PM

**To:** Ashley, Jackie <Ashley.Jackie@epa.gov>; Davis, Alison <Davis.Alison@epa.gov>

**Cc:** Koerber, Mike <Koerber.Mike@epa.gov>

**Subject:** EtO updates for the Monday ADD call

Jackie/Alison:

I'm on the agenda for the 4:00 pm ADD call. Is there anything you can help me with in regard to "Bills in Congress" and the NRDC item?

4:20 – EtO Update, Lew Weinstock (OAQPS)

- Status of Willowbrook
- Bills in Congress
- NRDC listing of sterilizes across the country.

Lewis Weinstock | Office of Air Quality Planning & Standards | U.S. Environmental Protection Agency | Research Triangle Park, NC 27711 | Phone: 919-541-3661|

**From:** Witt, Jon  
**To:** Cortelyou-Lee, Jan; Koerber, Mike; Bremer, Kristen; Shappley, Ned; Rimer, Kelly; Weinstock, Lewis; Mckelvey, Laura; Wilson, Holly; Strum, Madeleine; Caparoso, Jennifer; Davis, Alison  
**Subject:** RE: Information "Packet" in prep for Willowbrook Community Meeting -  
**Date:** Tuesday, November 20, 2018 6:18:19 AM  
**Attachments:** Timeline Content jww.docx

---

Hi all,

Attached are additional items for the timeline related to the sterilizers rulemaking history, including bullets on the removal of back vent control requirements in 2001. Please let me know if there are any questions.

Thanks,  
Jonathan

---

**From:** Cortelyou-Lee, Jan  
**Sent:** Thursday, November 15, 2018 10:57 AM  
**To:** Koerber, Mike <Koerber.Mike@epa.gov>; Bremer, Kristen <Bremer.Kristen@epa.gov>; Shappley, Ned <Shappley.Ned@epa.gov>; Rimer, Kelly <Rimer.Kelly@epa.gov>; Weinstock, Lewis <Weinstock.Lewis@epa.gov>; Mckelvey, Laura <Mckelvey.Laura@epa.gov>; Wilson, Holly <Wilson.Holly@epa.gov>; Strum, Madeleine <Strum.Madeleine@epa.gov>; Witt, Jon <Witt.Jon@epa.gov>; Caparoso, Jennifer <Caparoso.Jennifer@epa.gov>; Davis, Alison <Davis.Alison@epa.gov>  
**Subject:** Information "Packet" in prep for Willowbrook Community Meeting -

Hey folks – I'm sharing drafts I pulled together yesterday responding to requests from the Willowbrook Community for information in advance of the meeting 11.29.18.

## Ex. 5 Deliberative Process (DP)

Finally – please send me comments as you are able. I don't need the whole batch at once – I'd like to finalize most of these next week.

**From:** [Wehrum, Bill](#)  
**To:** [Woods, Clint](#)  
**Subject:** Re: NATA  
**Date:** Sunday, August 19, 2018 6:13:56 AM

---

Thanks.

---

Bill Wehrum  
Assistant Administrator  
Office of Air and Radiation  
U.S. Environmental Protection Agency  
(202) 564-7404

On Aug 19, 2018, at 5:59 AM, Woods, Clint <[woods.clint@epa.gov](mailto:woods.clint@epa.gov)> wrote:

FYI ahead of meeting with Grumbles

Begin forwarded message:

**From:** "Koerber, Mike" <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)>  
**Date:** August 18, 2018 at 11:34:47 AM EDT  
**To:** "Woods, Clint" <[woods.clint@epa.gov](mailto:woods.clint@epa.gov)>  
**Cc:** "Davis, Alison" <[Davis.Alison@epa.gov](mailto:Davis.Alison@epa.gov)>, "Bremer, Kristen" <[Bremer.Kristen@epa.gov](mailto:Bremer.Kristen@epa.gov)>, "Sasser, Erika" <[Sasser.Erika@epa.gov](mailto:Sasser.Erika@epa.gov)>, "Rimer, Kelly" <[Rimer.Kelly@epa.gov](mailto:Rimer.Kelly@epa.gov)>  
**Subject:** Fwd: NATA

FYI - Just talked with Tad. I explained about the strong interest in making the data publicly available and our desire to align with the forthcoming action of another federal agency. He didn't think that was compelling enough to forego the 2-week preview period and said we can expect to get further calls from ECOS on Monday. I got the sense that he might be okay with getting at least a few more days.

Mike

Sent from my iPhone

Begin forwarded message:

**From:** George Aburn -MDE-  
<[george.aburn@maryland.gov](mailto:george.aburn@maryland.gov)>  
**Date:** August 17, 2018 at 6:46:07 PM EDT  
**To:** "Koerber, Mike" <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)>  
<[koerber.mike@epa.gov](mailto:koerber.mike@epa.gov)>

**Cc:** "Fernandez.Cristina@epa.gov"  
<fernandez.cristina@epa.gov>, chow.alice@epa.gov  
**Subject:** NATA

I have my ECOS Air Committee hat on.

Just a heads up. Public release on 8/22 before states  
have even had a  
chance to understand analysis is a big problem.

What's the rush. What's driving this?

Seems like a 2 week pause would be a good thing for  
everybody.

Feel free to call me over the weekend.

Tad

Cell: 443 829 3652

Sent from my iPhone

--

Click here

<[http://www.doit.state.md.us/selectsurvey/TakeSurvey.aspx?  
agencycode=MDE&SurveyID=86M2956](http://www.doit.state.md.us/selectsurvey/TakeSurvey.aspx?agencycode=MDE&SurveyID=86M2956)>

to complete a three question customer experience survey.

**From:** Ward, Hillary  
**To:** Koerber, Mike; Sasser, Erika; Rimer, Kelly; Vasu, Amy; Hetes, Bob; Jones, Rhea; Srivastava, Ravi; Lassiter, Penny; Topham, Nathan; French, Chuck  
**Subject:** Materials: OAR Use of IRIS  
**Date:** Tuesday, June 4, 2019 4:30:16 AM  
**Attachments:** OAR Use of IRIS briefing Wehrum June 4 2019.docx

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Please see the attached materials for the following meeting:

6/4/19, 3:00-3:45, OAR Use of IRIS

Hillary Ward  
USEPA, Office of Air Quality Planning and Standards  
(919)541-3154

**From:** [Mills, Kathy](#)  
**To:** [Ward, Hillary](#); [Koerber, Mike](#); [McKinney, Voronina](#)  
**Cc:** [South, Peter](#); [Cozzie, David](#); [Lassiter, Penny](#); [Fruh, Steve](#); [Witt, Jon](#); [Ashley, John](#); [Crowley, Kate](#)  
**Subject:** 5/14 EtO Sterilization NESHAP tech review - pager attached  
**Date:** Tuesday, May 14, 2019 6:25:53 AM  
**Attachments:** [EtOInfoBriefing5.14.19Finaldocx.docx](#)

---

5/14 EtO Sterilization NESHAP tech review - pager attached.

Kathy "KB Mills ~ SPPD ~ U. S. EPA, OAQPS ~ 919-541-1599

**From:** [DeLuca, Isabel](#)  
**To:** [Wehrum, Bill](#); [Woods, Clint](#)  
**Cc:** [Millet, John](#)  
**Subject:** NATA comms  
**Date:** Tuesday, August 21, 2018 3:46:12 PM  
**Attachments:** [20180821-Sterigenics\\_desk\\_statement.docx](#)  
[NATA\\_desk\\_statement\\_8.21.18.docx](#)  
[Ethylene Oxide Fact Sheet.Final.8.21.18.pdf](#)  
[2014 NATA Overview Fact Sheet..pdf](#)

---

Hi Bill and Clint,

The R5 desk statement on Sterigenics is attached for your review. I've also attached the HQ desk statement, NATA fact sheet, and EtO fact sheets – OPA sent these to the regions this afternoon.

Clint— if the R5 desk statement looks ok to you, can you please forward to John Konkus (and cc me so I know it's final too)? John wants to make sure this has cleared OAR IO before he approves.

The plan is to post NATA tomorrow at 2 pm.

Thanks,  
Isabel

**Isabel DeLuca**

Office of Air and Radiation, US EPA  
(202) 343-9247

**From:** Ashley, Jackie  
**To:** Koerber, Mike; Weinstock, Lewis; Rimer, Kelly; Smith, Darcie  
**Cc:** Terry, Sara; Davis, Alison  
**Subject:** FYI - Final TA on EtO monitoring language for House Approps  
**Date:** Monday, May 6, 2019 5:15:02 AM  
**Attachments:** TA request to EPA OAR responses 5.3.2019.docx

---

FYI – The final technical assistance on the EtO monitoring language from House Appropriations is attached. It was sent forward on Friday after OAR IO review. It begins on p. 2 and is also copied it into the body of this email.

Let me know if you have questions.

-Jackie

--

### **Ethylene Oxide**

Provided, that of the funds included in this heading, \$3,000,000 shall be used, in coordination with state and local public health departments and the Agency for Toxic Substance and Disease Registry, to conduct ambient air monitoring for ethylene oxide in communities identified by the National Air Toxic Assessment to face high levels of ethylene oxide emissions.

- Is \$3 million enough to conduct this air monitoring? How many communities in the NATA have been ID'ed as having high levels of ethylene oxide?

**RESPONSE: Technical assistance from OAOPS/OAR IO**

## **Ex. 5 Deliberative Process (DP)**

# **Ex. 5 Deliberative Process (DP)**

# **Ex. 5 Deliberative Process (DP)**

-----  
Jackie Ashley - US EPA - Office of Air Quality Planning and Standards - 919-541-7664 – [ashley.jackie@epa.gov](mailto:ashley.jackie@epa.gov)

## **REPORT LANGUAGE**

### **RFS RIN Market Study**

The Committee is concerned with the fraud, RIN price volatility, and market abuses that are occurring in the RIN market. The Committee directs EPA to work with the Treasury Department and CFTC to help determine factors, in addition to supply and demand, that have been causing extraordinary volatility in the price of RINs. In addition, Treasury and CFTC should provide EPA with advice on how to improve the RIN market to combat market manipulation and fraud. The Committee directs EPA to report back to the Committee within 90 days of enactment of this Act, with recommendations to improve the integrity of the RIN market and EPA's oversight of the market.

- Who regulates the primary and secondary markets for RINs?

### **RESPONSE: Technical assistance from OTAQ**

EPA has primary authority to write regulations to ensure the validity of RINs (i.e., prevent fraud) and how RINs are traded. CFTC has authority to take an enforcement action on participant behaviors that may violate the anti-fraud and anti-manipulation provisions of the Commodity Exchange Act. For example, Section 9(a)(2) of the CEA, 7 U.S.C. § 13(a)(2) (2012) states that it is a felony for “Any person to manipulate or attempt to manipulate the price of any commodity in interstate commerce...or to corner or attempt to corner any such commodity or knowingly to deliver or cause to be delivered for transmission through the mails or interstate commerce by telegraph, telephone, wireless, or other means of communication false or misleading or knowingly inaccurate reports concerning crop or market information or conditions that affect or tend to affect the price of any commodity in interstate commerce.” Section 6(c)(1) of the CEA, 7 U.S.C. § 9(1) (2012), titled Prohibition Against Manipulation, states that “it shall be unlawful for any person, directly or indirectly, to use or employ, or attempt to use or employ, in connection with...a contract of sale of any commodity in interstate commerce...any manipulative or deceptive device or contrivance....”

- Who regulates the derivatives markets?

### **RESPONSE: Technical assistance from OTAQ**

CFTC has authority to regulate and enforce the futures/derivative markets.

- What has EPA implemented already to regulate the market, and is it planning future steps like setting position or trading limits?

### **RESPONSE: Technical assistance from OTAQ**

EPA has proposed and plans to finalize certain market reforms that are meant to better assess and address potential concerns of market manipulation. EPA has taken steps to increase transparency in the program and market by publishing aggregated (non CBI) public data on RIN transactions and activities on the EPA website <https://www.epa.gov/fuels-registration-reporting-and->

compliance-help/public-data-renewable-fuel-standard. In addition, EPA has put in place a voluntary Quality Assurance Program that is intended to assure reasonable oversight of RIN generation and promote greater liquidity in the RIN market. The program includes elements designed to make it possible to verify the validity of RINs and to address RINs that become invalid downstream of a renewable fuel producer.

## **BILL LANGUAGE**

### **10-20-30 Language in STAG Accounts**

Notwithstanding any other provision of law, of the amounts appropriated for [infrastructure grant program X], at least 10 percent shall be allocated for assistance in persistent poverty counties, if such allocations are otherwise authorized: Provided, That for purposes of this section, the term persistent poverty counties means any county that has had 20 percent or more of its population living in poverty over the past 30 years, as measured by the 1990 and 2000 decennial censuses and the most recent Small Area Income and Poverty Estimates.

- This language has been carried for Brownfields in the past. Would EPA be able to apply a similar targeting formula for these other STAG Infrastructure grants?
  - Alaska Native Villages
  - DERA
  - US-Mexico Border
- How close are these grant programs in achieving this 10% funding goal already? In other words, would imposing this targeting goal result in a radical shift in which counties receive money, just a minor shift, or are the programs meeting/exceeding the 10% targeting goal already, without a requirement to do so?

### **RESPONSE: Technical assistance from OTAQ**

After consideration and analysis, EPA believes that adding a 10% Persistent Poverty Counties requirement to the DERA program would be very challenging and could be inconsistent with the statutory priorities of the DERA program. The basic premise of the DERA program is the implementation of cost-effective mobile source projects in high-population, poor air quality areas; per appropriations language, 70% of grants must be made available to these areas. The DERA program already targets lower SES areas through its emphasis on environmental justice communities near ports, and goods movement and distribution centers. EPA would be glad to discuss specifics about how the DERA program operates and options for moving forward. EPA will follow up with committee staff to schedule a call.

### **Ethylene Oxide**

Provided, that of the funds included in this heading, \$3,000,000 shall be used, in coordination with state and local public health departments and the Agency for Toxic Substance and Disease

Registry, to conduct ambient air monitoring for ethylene oxide in communities identified by the National Air Toxic Assessment to face high levels of ethylene oxide emissions.

- Is \$3 million enough to conduct this air monitoring? How many communities in the NATA have been ID'ed as having high levels of ethylene oxide?

**RESPONSE: Technical assistance from OAQPS/OAR IO**

EPA and its state and local environmental agency partners have significant work underway to understand, characterize, and address ethylene oxide emissions and concentrations through national regulatory changes as well as site-specific opportunities. Ambient air quality monitoring is not necessary for evaluating potential risk from particular facilities. There are other tools available to assess risk from individual sources, and resources may be utilized more effectively through other state, local, or federal activities related to ethylene oxide, including stack testing, reviewing permits, overseeing the installation of pollution controls, air dispersion modeling, monitoring technology development, emissions inventory analysis, risk communication, and regulatory development.

The current technology available for monitoring ethylene oxide in the outdoor air does not allow us to measure this pollutant at all levels of concern. In addition, depending on the existence of other mix of sources in an area (which may contribute to the background level), monitoring alone may not be enough to determine an individual facility's contribution to ethylene oxide in the outdoor air.

Background levels for ethylene oxide are not well understood. Because of this, EPA believes that analyzing air quality samples from existing monitoring sites is the best option at this time for understanding whether background ethylene oxide is present in the air broadly across the country, and, if it is present, whether and how levels vary spatially on a national basis. EPA is not adding monitoring equipment at these sites; rather, the Agency is having laboratories analyze air quality samples for ethylene oxide in addition to other air toxics.

We would suggest that any appropriated funds be added to the existing STAG allocation distributed to the state and local air monitoring organizations. These state/local monitoring organizations have long-standing experience in air toxics measurement and would best be able to design and deploy monitoring sites in an expeditious manner.

We estimate it would cost about \$175,000 per year to adequately monitor around a facility. Based on this estimate, \$3,000,000 would fund monitoring at about 17 facilities for one year.

You may also want to consider broader criteria (i.e., not just NATA) to provide additional flexibility to states and communities. Other areas of interest may be identified as we learn more about emissions of ethylene oxide. For example, as part of EPA's two-pronged approach to address emissions of ethylene oxide around the country, the Agency is gathering additional information on ethylene oxide emissions to both help EPA as it evaluates opportunities to reduce emissions.

EPA is following a two-pronged strategy for addressing ethylene oxide emissions nationwide:

1. We are reviewing Clean Air Act regulations for facilities that emit ethylene oxide to ensure that they protect the public from significant risk. There are two reviews in progress:
  - The air toxics standards for miscellaneous organic chemical manufacturing
  - Air toxics standards for commercial sterilizers
  - We expect to issue proposed updates to both of these rules this summer.
2. For areas identified as having the highest potential risk, we are gathering additional information on emissions of ethylene oxide
  - This will support regulatory review
  - It also will help us identify any near-term emission reduction opportunities.

EPA's [ [HYPERLINK "https://www.epa.gov/national-air-toxics-assessment/2014-national-air-toxics-assessment"](https://www.epa.gov/national-air-toxics-assessment/2014-national-air-toxics-assessment) ] (NATA) is a screening tool, intended to help EPA and state, local, and tribal air agencies determine if areas, pollutants, or types of pollution sources need to be examined further to better understand risks to public health. NATA does not provide risk estimates for any individual facility, however NATA results can be used to identify pollutants and types of pollution sources (e.g., point sources) of greatest concern and to help set priorities for the collection of additional information. In the 2014 NATA, EPA identified 19 metropolitan statistical areas (MSAs) containing census tracts with elevated cancer risks from exposure to air toxics. Of those 19 MSAs, 18 of them have elevated risks due to emissions of ethylene oxide.

NATA has some limitations you should consider when looking at the results:

- Data gaps
- Pollutant concentrations used in risk calculations based on computer model simulations, not direct measurements
- Default assumptions (used routinely in any risk assessment)
- Assessment design limitations (intended to address some questions but not others)
- Regional differences in emissions data completeness

Also keep in mind that NATA's results:

- Apply best to larger areas, not specific places;
- Apply to groups, not to specific people;
- Include direct impacts from U.S. sources only;
- Apply only to the analysis year (when the source data were collected);
- Assume a person breathes the air toxics emitted in the analysis every day for 70 years;
- Only reflect exposures and risks from certain air toxics;
- Only include toxics released into the outdoor air;
- Estimate health impacts only from breathing air toxics;

- Reflect just some of the variation in background pollutant concentrations;
- May give concentrations that are too high or too low for some air toxics and in some places;
- Make some assumptions when data are missing or in error;
- May not accurately capture sources that emit only at certain times (e.g., prescribed burning or facilities with short-term deviations such as startups, shutdowns, malfunctions and upsets);
- Include risk estimates that are uncertain.

**From:** [Sasser, Erika](#)  
**To:** [Koerber, Mike](#); [Tsirigotis, Peter](#)  
**Cc:** [Langdon, Robin](#); [Wayland, Richard](#); [Cozzie, David](#); [Smith, Darcie](#); [Davis, Alison](#)  
**Subject:** Toxics Materials for Monday  
**Date:** Friday, July 6, 2018 10:35:22 AM  
**Attachments:** [OAR - Air Toxics Discussion Paper v4.docx](#)

---

Peter and Mike—

Attached are the revised materials for Monday's meeting with Bill on EtO and the air toxics approach, reflecting our conversations earlier this week and the edits I discussed with Mike. If these look ok, please send up.

Thanks,  
Erika

**From:** McLamb, Marguerite  
**To:** South, Peter; Jones, Rhea; Langdon, Robin; Davis, Alison; Bremer, Kristen  
**Cc:** Koerber, Mike; Cozzie, David; Lassiter, Penny; Rimer, Kelly; Rodman, Sonja; Thompson, Fred  
**Subject:** RE: EtO materials for tomorrow's meeting with Bill W--due at 9:00 am Wed  
**Date:** Wednesday, July 25, 2018 5:59:48 AM  
**Attachments:** EtO\_Regulatory\_Options\_7.25.2018\_SPPD.docx

---

Pete,  
Attached is a file with SPPD's material. Please let us know if you have any questions.  
Best,  
Marguerite

\*\*\*\*\*

Marguerite E. McLamb  
Policy Advisor  
Sector Policies and Programs Division  
Office of Air Quality Planning & Standards  
U.S. Environmental Protection Agency  
Research Triangle Park, NC 27711  
Phone (office): (919) 541-7858  
Phone (mobile): (919) 491-7514  
Fax: (919) 541-4991  
[mclamb.marguerite@epa.gov](mailto:mclamb.marguerite@epa.gov)

---

From: South, Peter  
Sent: Tuesday, July 24, 2018 5:03 PM  
To: Jones, Rhea; Langdon, Robin; McLamb, Marguerite; Davis, Alison; Bremer, Kristen  
Cc: Koerber, Mike  
Subject: EtO materials for tomorrow's meeting with Bill W--due at 9:00 am Wed

Mike has requested the EtO meeting materials by 9:00 am tomorrow morning. We're planning on sending up by 9:30.

Let me know if you have any questions.

Thanks.

Pete South  
OAR/OAQPS/IO  
U.S. EPA  
office: 919 541-5359  
cell: 919 599-7213

**From:** Koerber, Mike  
**To:** Woods, Clint; Lewis, Josh; Tsirigotis, Peter  
**Cc:** Davis, Alison; Sasser, Erika; "Wayland, Richard"; Cozzie, David  
**Subject:** Draft talking points  
**Date:** Thursday, July 26, 2018 5:03:00 AM  
**Attachments:** Suggested key points to cover with RAs july 26.docx

---

Clint: Here are draft talking points to use for today's call with the RAs. Let me know what you think. My understanding is that Bill intends to kick-off the call and then hand it to OAQPS. Thanks.

Mike

**From:** Arnold, David  
**To:** Koerber, Mike; Smith, Darcie; Perez, Idalia  
**Cc:** Chow, Alice; Gross-Davis, CarolAnn; Fry, Jessica; Fernandez, Cristina  
**Subject:** NATA Priority Facility Decision Criteria  
**Date:** Thursday, August 2, 2018 1:11:42 PM

---

Mike/Darcie/Idalia,

At last week's AA/RA call on the EtO / NATA issue, Bill Wehrum asked the Regions for suggested decision criteria to prioritize our evaluation of EtO facilities.

Here are some of the criteria Region 3 plans to use:

- What are the total EtO emissions?
- What are the total facility emissions?
- Are the facilities located in EJ Areas?
- Are there any current controls?
- What are the cumulative impacts from ethylene oxide and the other air toxics released at the facilities?
- Trending population. Are there areas that have a large growth in population within the last few years?
- What is the compliance history/status of the facility?
- What is the Title V permit status (for major sources)
- Are there any pending construction permit applications?

Let me know if I am sending this to the right people or not.

Dave

David L. Arnold  
Deputy Director  
Air Protection Division  
US EPA - Region 3  
1650 Arch Street  
215-814-2172

**From:** [South, Peter](#)  
**To:** [Hamett, Bill](#); [Koerber, Mike](#); [McKinney, Voronina](#); [OACPS WQPS](#); [OAR Briefings](#)  
**Cc:** [Tsingotis, Peter](#); [Koerber, Mike](#); [Sasser, Enika](#); [Wayland, Richard](#); [Langdon, Robin](#); [Palma, Ted](#); [Truesdell, Raymond](#); [Riha, Kristin](#); [Bremer, Kristen](#); [Davis, Alison](#); [Cozzie, David](#); [Jones, Rhea](#); [Smith, Darcie](#); [Shelov, David](#); [Rimar, Kelly](#); [Thompson, Fred](#); [Mozingo, Kristal](#); [Henby, James](#); [McGaha, Debbie](#)  
**Subject:** Processes and Mechanism for Addressing Air Toxics: Materials in prep for tomorrow's Air Toxics Meeting with Bill W  
**Date:** Tuesday, July 10, 2018 1:54:00 PM  
**Attachments:** [image001.png](#)  
[Air Toxics Discussion 07.11.18.pdf](#)

---

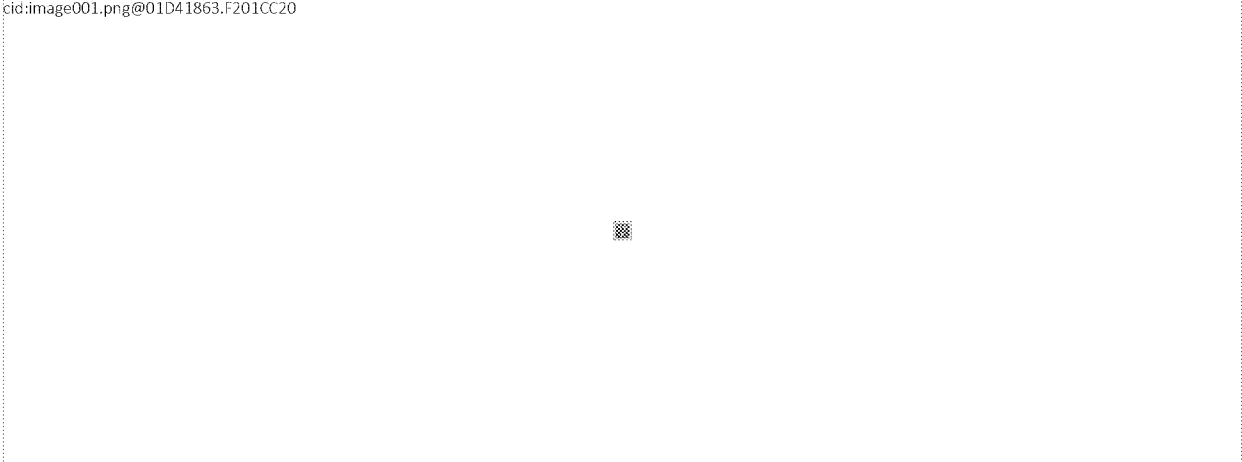
I have attached the briefing materials in prep for tomorrow's air toxics meeting with Bill.

Please call me or Mike Koerber with any questions relating to this information.

Thank you.

Pete South  
OAR/OAQPS/IO  
U.S. EPA  
office: 919 541-5359  
cell: 919 599-7213


cid:image001.png@01D41863.F201CC20



Organizer ☐ Rakosnik, Delaney on behalf of ☐ Wehrum, Bill

Subject Processes and mechanisms for Addressing Air Toxics

Location WJC - N 5400 + Video with RTP + **Ex. 6 Personal Privacy (PP)**

Start time Wed 7/11/2018  12:30 PM ▼ ☐ All day event

End time Wed 7/11/2018  1:30 PM ▼

**TO:** Bill Wehrum, David Harlow, Clint Woods, Josh Lewis, Peter Tsirigotis, Mike Koerber, Erika Sasser, Richard Wayland, Robin Langdon, Da  
Ted Palma, Raymond Truesdell, Kristin Riha, Rhea Jones, Kristen Bremer, Alison Davis, David Cozzie



FW: Meeting  
request for Air T...



**From:** [Smith, Darcie](#)  
**To:** [Koerber, Mike](#)  
**Cc:** [Sasser, Erika](#); [Jones, Rhea](#); [Rimer, Kelly](#); [Truesdell, Raymond](#); [Riha, Kristin](#); [Davis, Alison](#); [Bremer, Kristen](#)  
**Subject:** Regional data verification status  
**Date:** Wednesday, August 15, 2018 1:14:23 PM  
**Attachments:** [image002.png](#)  
[image004.png](#)

---

For the regional data verification of emissions used in NATA that was supposed to happen by today:

## Ex. 5 Deliberative Process (DP)

For the most part, the facilities have been contacted by the region or state.

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
 919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

**From:** Koerber, Mike  
**To:** Mary Douglas; Jason Sloan  
**Subject:** NATA key messages  
**Date:** Wednesday, August 22, 2018 6:03:00 AM  
**Attachments:** NATA Key Talking Points. 8.20.18 Version for States .docx

---

Mary, Jason: As a follow-up to my call this morning, here are the key messages that we prepared for states. (Note, this is the same document that was sent to the EPA Regional Offices on Monday for distribution to states.) Please let me know if you have any questions.

Mike

**From:** [Witt, Jon](#)  
**To:** [Koerber, Mike](#); [Davis, Alison](#); [Bremer, Kristen](#)  
**Subject:** RE: Draft slides for Next Steps portion of May 29 agenda  
**Date:** Tuesday, May 21, 2019 1:09:04 PM  
**Attachments:** [EPA National Rule for Commercial Sterilizers - May 29jw.pptx](#)

---

Looks good to me. Some minor edits/comments attached.

---

**From:** Koerber, Mike  
**Sent:** Tuesday, May 21, 2019 4:01 PM  
**To:** Davis, Alison <[Davis.Alison@epa.gov](mailto:Davis.Alison@epa.gov)>; Bremer, Kristen <[Bremer.Kristen@epa.gov](mailto:Bremer.Kristen@epa.gov)>; Witt, Jon <[Witt.Jon@epa.gov](mailto:Witt.Jon@epa.gov)>  
**Subject:** Draft slides for Next Steps portion of May 29 agenda

Comments?

**From:** [Woods, Clint](#)  
**To:** [Koerber, Mike](#)  
**Subject:** Re: Draft revision to EtO language  
**Date:** Wednesday, December 12, 2018 5:55:38 AM

---

Thanks for heads up - Spoke to her late yesterday. We are on same page but she is flagging for Acting Admin ahead of signature

On Dec 11, 2018, at 4:51 PM, Koerber, Mike <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)> wrote:

Clint – Just a heads up that you might get a call from Brittany about the EtO language on pages 52-53. Recall, you and I worked on this language in early November.

Mike

---

**From:** French, Chuck  
**Sent:** Tuesday, December 11, 2018 4:06 PM  
**To:** South, Peter <[South.Peter@epa.gov](mailto:South.Peter@epa.gov)>  
**Cc:** Cozzie, David <[Cozzie.David@epa.gov](mailto:Cozzie.David@epa.gov)>; Rimer, Kelly <[Rimer.Kelly@epa.gov](mailto:Rimer.Kelly@epa.gov)>; Topham, Nathan <[Topham.Nathan@epa.gov](mailto:Topham.Nathan@epa.gov)>  
**Subject:** FW: Draft revision to EtO language

Hi Pete,

## Ex. 5 Deliberative Process (DP)

### Ex. 5 Deliberative Process (DP)

The email below from Nate provides the details and some possible suggestions to address the issue. The package is at OP, with signature expected soon. I heard that OP staff have raised this issue to AA level (Brittany Bolen) and that OP may contact Clint Woods to discuss.

Let me know if you have questions.

Thanks!

Chuck

---

**From:** Topham, Nathan  
**Sent:** Tuesday, December 11, 2018 1:16 PM  
**To:** French, Chuck <[French.Chuck@epa.gov](mailto:French.Chuck@epa.gov)>  
**Cc:** Peffers, Mel <[Peffers.Mel@epa.gov](mailto:Peffers.Mel@epa.gov)>; Tierney, Jan <[tierney.jan@epa.gov](mailto:tierney.jan@epa.gov)>; Benner, Tim <[Benner.Tim@epa.gov](mailto:Benner.Tim@epa.gov)>; Shrager, Brian <[Shrager.Brian@epa.gov](mailto:Shrager.Brian@epa.gov)>  
**Subject:** Draft revision to EtO language

Hey Chuck,

## **Ex. 5 Deliberative Process (DP)**

This is something you'll likely want to mention to Mike Koerber so he can get a little background from prior to hearing about it from Clint or other offices.

<FRN Hydrochloric Acid Production RTR Proposal  
PreambleRule\_11192018.docx>

**From:** [Woods, Clint](#)  
**To:** [Koerber, Mike](#)  
**Subject:** Re: HCI RTR Blue Folder  
**Date:** Wednesday, November 21, 2018 1:13:13 PM

---

Finally got a chance to talk with Bill and he likes the language here

On Nov 15, 2018, at 10:19 AM, Koerber, Mike <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)> wrote:

Thanks, Clint. Yes, 4:30 pm is great. I'll plan to call you.

Mike

---

**From:** Woods, Clint  
**Sent:** Thursday, November 15, 2018 10:11 AM  
**To:** Koerber, Mike <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)>  
**Subject:** Re: HCI RTR Blue Folder

Sorry for delay - I'm belatedly up to speed on maintenance plan guidance, and comfortable with the materials. Waiting for feedback on #1 from Bill & Harlow. Could we touch base this afternoon, maybe 4:00 or 4:30?

On Nov 14, 2018, at 5:42 PM, Koerber, Mike <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)> wrote:

Clint: When you get a chance on Thursday, I'd like to touch base with you on three things:

1. HCI package – see below
2. Ozone Maintenance Plan Guidance (see my Nov 5 email)
3. A request from Colorado State University for an interview on “policy barriers to prescribed fire”

Thanks.

---

**From:** Koerber, Mike  
**Sent:** Friday, November 09, 2018 1:09 PM  
**To:** Woods, Clint <[woods.Clint@epa.gov](mailto:woods.Clint@epa.gov)>  
**Subject:** FW: HCI RTR Blue Folder

Clint: Here are edits on top of your suggested changes. Let me know if you are comfortable with this new language. Thanks.

Mike

## **Ex. 5 Deliberative Process (DP)**

## Ex. 5 Deliberative Process (DP)

---

**From:** Woods, Clint  
**Sent:** Monday, November 05, 2018 2:50 PM  
**To:** Koerber, Mike <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)>  
**Subject:** RE: HCI RTR Blue Folder

Mike,

Attached contains a couple additions – I'd welcome the chance to discuss further. Thanks!

Clint Woods  
Deputy Assistant Administrator  
Office of Air and Radiation, U.S. EPA

202.564.6562

---

**From:** Koerber, Mike  
**Sent:** Wednesday, October 31, 2018 4:32 PM  
**To:** Woods, Clint <[woods.clint@epa.gov](mailto:woods.clint@epa.gov)>  
**Subject:** FW: HCI RTR Blue Folder

Clint: As a follow-up to our conversation yesterday about the Hydrochloric Acid RTR, see attached draft NPRM. No need to read the whole thing now – just look at the added text on pages 53-54 re: EtO. I took this language directly from the EtO fact sheet on our website – with a small tweak by SPPD. If this looks okay to you, then we will move this forward for signature – already received OMB non-significance.

Mike

---

**From:** French, Chuck  
**Sent:** Wednesday, October 31, 2018 3:25 PM  
**To:** Koerber, Mike <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)>  
**Cc:** Topham, Nathan <[Topham.Nathan@epa.gov](mailto:Topham.Nathan@epa.gov)>; South, Peter <[South.Peter@epa.gov](mailto:South.Peter@epa.gov)>  
**Subject:** RE: HCI RTR Blue Folder

Hi Mike,

Sorry for the delay. Attached are a few suggested minor edits to the text on pages 53-54.

Let us know if you have questions.

Thanks!

Chuck

---

**From:** Koerber, Mike  
**Sent:** Tuesday, October 30, 2018 10:15 AM  
**To:** French, Chuck <[French.Chuck@epa.gov](mailto:French.Chuck@epa.gov)>  
**Cc:** Topham, Nathan <[Topham.Nathan@epa.gov](mailto:Topham.Nathan@epa.gov)>; South, Peter <[South.Peter@epa.gov](mailto:South.Peter@epa.gov)>  
**Subject:** RE: HCI RTR Blue Folder

Thanks, Chuck. I added text on pages 53-54. Let me know if it makes sense to you. After I hear back from you, then I will run it by Clint to make sure it's what he's looking for.

Mike

---

**From:** French, Chuck

**Sent:** Tuesday, October 30, 2018 9:42 AM

**To:** Koerber, Mike <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)>

**Cc:** Topham, Nathan <[Topham.Nathan@epa.gov](mailto:Topham.Nathan@epa.gov)>; South, Peter <[South.Peter@epa.gov](mailto:South.Peter@epa.gov)>

**Subject:** FW: HCI RTR Blue Folder

Hi Mike,

As we discussed, attached is the latest version of the HCI Production RTR preamble. The discussion of ethylene oxide and facility-wide risks is on pages 50 and 53. Please let us know what additional text and/or edits that you recommend regarding this topic.

Also, let us know if you have questions.

Thanks!

Chuck

---

**From:** Eck, Janet

**Sent:** Monday, October 29, 2018 8:48 PM

**To:** French, Chuck <[French.Chuck@epa.gov](mailto:French.Chuck@epa.gov)>

**Cc:** South, Peter <[South.Peter@epa.gov](mailto:South.Peter@epa.gov)>; Topham, Nathan <[Topham.Nathan@epa.gov](mailto:Topham.Nathan@epa.gov)>

**Subject:** FW: HCI RTR Blue Folder

Chuck, I will have finished my review tomorrow and go over everything w/Nate. This is the latest. Thanks.

---

**From:** French, Chuck

**Sent:** Monday, October 29, 2018 5:42 PM

**To:** South, Peter <[South.Peter@epa.gov](mailto:South.Peter@epa.gov)>; Topham, Nathan <[Topham.Nathan@epa.gov](mailto:Topham.Nathan@epa.gov)>; Eck, Janet <[Eck.Janet@epa.gov](mailto:Eck.Janet@epa.gov)>

**Subject:** RE: HCI RTR Blue Folder

Hi All,

Can you please send me the latest version of the HCI RTR proposal preamble?

Thanks!

Chuck

---

**From:** South, Peter  
**Sent:** Friday, October 26, 2018 10:20 AM  
**To:** French, Chuck <[French.Chuck@epa.gov](mailto:French.Chuck@epa.gov)>  
**Subject:** Re: HCI RTR Blue Folder

Great. Thanks, Chuck.

Sent from my iPhone

On Oct 26, 2018, at 10:19 AM, French, Chuck <[French.Chuck@epa.gov](mailto:French.Chuck@epa.gov)> wrote:

Pete,

See below and attached.

Thanks!

Chuck

---

**From:** Topham, Nathan  
**Sent:** Thursday, October 25, 2018 1:11 PM  
**To:** Eck, Janet <[Eck.Janet@epa.gov](mailto:Eck.Janet@epa.gov)>  
**Cc:** French, Chuck <[French.Chuck@epa.gov](mailto:French.Chuck@epa.gov)>  
**Subject:** HCI RTR Blue Folder

Hey Janet,

Here are items for the HCI proposal blue folder. OGC is hoping Justin will respond today with whether he needs to review things. If not, they'll send their concurrence and said they'll copy you. Adrian has the signed typesetting request.

John Ashley has reviewed the communications materials and he sent them to PACS and got their comments as well.

I'm out of the office from 1:30 today and out tomorrow. I've got my office phone forwarding to my cell though, so if you have any questions, let me know.

<HCI Production ICR 2032.09 Supporting

Statement\_10252018.docx>

<HCl RTR Proposal PreambleRule\_10252018.docx>

<HCl Production RTR Post-It\_10252018.docx>

<HCl Production RTR Action Memo\_10252018.docx>

<Hydrochloric Acid RTR Fact Sheet 10252018.docx>

<HCl Production RTR Comm Plan\_10252018.docx>

<2016 Action Information HCl RTR\_10252018.doc>

.....  
.....  
<HCl RTR Proposal PreambleRule\_10272018 MK-SPPD-edits io.docx>

.....  
[1] In particular, the EPA has identified limitations to consider when looking at the results (e.g., data gaps, default assumptions, and regional differences in emissions data completeness). A number of other aspects of the results are also worth nothing, such as the results apply best to larger areas, not specific places; apply only to the analysis year (when the source data were collected); and assume a person breathes the air toxics emitted in the analysis every day for 70 years. See <https://www.epa.gov/national-air-toxics-assessment/nata-limitations> for a more complete discussion.

**From:** [Witt, Jon](#)  
**To:** [Koerber, Mike](#)  
**Subject:** Sterilizer NESHAP Schedule Ideas  
**Date:** Wednesday, January 30, 2019 6:56:39 AM  
**Attachments:** [NESHAP 2018TR Schedule.docx](#)

---

Hi Mike,

In case there is a discussion on schedule with Bill today, Steve and I came up with some ideas (attached). We can also discuss them tomorrow morning, if you'd like.

Thanks,  
Jonathan

---

**Jonathan W. Witt, EI**

Environmental Engineer  
Office of Air Quality Planning and Standards  
EPA|OAR|OAQPS|SPPD|FIG  
109 T.W. Alexander Dr. | Mail Drop: E143-05 | Durham, NC 27703  
+1.919.541.5645 (work) | +1.919.541.7885 (fax)

**From:** Mills, Kathy  
**To:** Lessard, Patrick; Koerber, Mike; McKinney, Voronina  
**Cc:** Cozzie, David; South, Peter; Thompson, Fred; Eck, Janet; Lassiter, Penny; Lavoie, Tegan; Caparoso, Jennifer  
**Subject:** 11/28 MON info briefing w/Peter  
**Date:** Wednesday, November 28, 2018 7:39:26 AM  
**Attachments:** MON Options Selection12.4.18.docx

---

11/28 MON info briefing w/Peter: We will refer to the attached 12/4 MON OS Wehrum briefing pager.  
KB

Kathy "KB Mills ~ SPPD ~ U. S. EPA, OAQPS ~ 919-541-1599

**From:** Shappley, Ned  
**To:** Weinstock, Lewis; Rimer, Kelly; Koerber, Mike; Smith, Darcie; Trinca, Laurie; Hemby, James; RTP-OAQPS-919-541-4248-AQAD/Phone-Line/RTP-OAQPS-BLDG-C  
**Subject:** EtO ambient monitoring

---

Quick discussion on ambient monitoring options in Willowbrook and follow-up from Region 5 calls.

Ned

Adding a call line

919-Ex. 6 Personal Privacy (PP)

**From:** [Koerber, Mike](#)  
**To:** [South, Peter](#)  
**Cc:** [French, Chuck](#)  
**Subject:** HCI Edits  
**Date:** Friday, November 16, 2018 12:49:00 PM  
**Attachments:** [HCI RTR Proposal PreambleRule\\_10272018 MK-SPPD-edits io MK.docx](#)

---

Pete – Here is (I think) the final edits on the HCI notice – see pages 53 and 54. I’m still waiting to get OAR approval, but Clint said that he’s okay with this and will be checking with Bill – today, I hope – to get his sign off. I’ll let you know when I hear back from Clint.

Mike

**From:** [Koerber, Mike](#)  
**To:** [Bremer, Kristen](#); [Davis, Alison](#)  
**Cc:** [Rimer, Kelly](#)  
**Subject:** FW: R5  
**Date:** Thursday, September 27, 2018 1:45:40 PM  
**Attachments:** [Sterigenics 8.22 web copy.pdf](#)

---

Please take a look and let me know what you think.

---

**From:** Woods, Clint  
**Sent:** Thursday, September 27, 2018 1:40 PM  
**To:** Koerber, Mike <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)>  
**Subject:** R5

Mike,

Attached is pdf of R5 website, which we had asked to reformat for national consistency. Can you take a look for content red flags or formatting changes we would suggest? Trying to get on read on whether this is a short term ask (post the pdf) or something where we could day a couple days to tighten up the page to match previous R6-type sites.

Thanks!

Clint Woods  
Deputy Assistant Administrator  
Office of Air and Radiation, U.S. EPA  
202.564.6562



**From:** Hanley, Jack (ATSDR/DCHI/CB)  
**To:** Rimer, Kelly  
**Cc:** Mckelvey, Laura; Reh, Chris (ATSDR/OA/OD); Moore, Susan (ATSDR/DCHI/SSB); mkj5@cdc.gov; Colledge, Michelle (ATSDR/DCHI/CB)  
**Subject:** RE: Request for ATSDR Participation at an Upcoming Public Meeting in Willowbrook IL  
**Date:** Tuesday, November 20, 2018 1:25:27 PM  
**Attachments:** Willowbrook community meeting agenda draft 11.13.18 (003).docx

---

Kelly,

Thank you for inviting ATSDR Region 5 Chicago office staff to attend and participate in the open house and community meeting on November 29, 2018 regarding ethylene oxide in Willowbrook, IL. CAPT Michelle Colledge, Ph.D., MPH and Mark Johnson, Ph.D. are approved to participate in the 2 events on the 29<sup>th</sup>. As requested, CAPT Colledge will participate in Session 1 to respond to questions related to ethylene oxide and what we know about the risks around the Sterigenics facilities in Willowbrook. We request that Dr. Johnson is allowed to participate in Session 3 to respond to questions related to future plans to inform and engage the community surrounding the Sterigenics facility. Participating in Session 3 would allow Dr. Johnson to inform the community of ATSDR's plans to continue our involvement in public health activities related to ethylene oxide emissions from the Steigenics facilities.

Please continue to coordinate with CAPT Colledge and Dr. Johnson in advance of the events on the 29<sup>th</sup>. We would also like to receive the specific issues, health concerns, and key community questions that EPA has identified in your pre-meetings with the community. We look forward to working with the EPA OAQPS on ethylene oxide emissions from Sterigenics facilities in Willowbrook.

Cordially,

Jack Hanley

Jack E. Hanley, MPH

Environmental Health Scientists  
Division of Community Health Investigation  
Agency for Toxic Substances and Disease Registry (ATSDR)

(W) 770-488-0736 | (C) 404-966-9713

Chamblee Campus, Building 106  
4770 Buford Highway, F59  
Chamblee, GA 30341

---

**From:** Rimer, Kelly <Rimer.Kelly@epa.gov>  
**Sent:** Monday, November 19, 2018 1:06 PM  
**To:** Reh, Chris (ATSDR/OA/OD) <cer2@cdc.gov>; Moore, Susan (ATSDR/DCHI/SSB) <sym8@cdc.gov>;

Hanley, Jack (ATSDR/DCHI/CB) <jah8@cdc.gov>

**Cc:** Mckelvey, Laura <Mckelvey.Laura@epa.gov>

**Subject:** Request for ATSDR Participation at an Upcoming Public Meeting in Willowbrook IL

Chris, Susan and Jack,

The purpose of this email is to formally request that ATSDR attend and participate in 2 events for the public on November 29 regarding ethylene oxide (EtO) in Willowbrook. The events are an afternoon open house and an evening community meeting.

We request that Michelle College, the author of the July 26, 2018 letter to Ed Nam of EPA Region 5, attend both events and (1) respond to questions regarding the analysis contained in the letter, (2) respond to health-related questions as appropriate given her expertise and her involvement in the effort. We have discussed the upcoming events with Michelle and also with Mark Johnson, and if ATSDR is cleared to attend, we will continue coordinating with them in advance of the 29<sup>th</sup>.

The purpose of the open house is for members of the community to meet with technical experts and ask questions on various topics related to EtO in the Willowbrook area. The intent is to be accessible to people who cannot attend the evening session. There will be several tables where experts will answer questions, including a table where federal experts will answer questions about risk and health. I will be at that table along with ATSDR (if cleared) and will handle questions directed to the EPA. Other EPA experts will cover monitoring and state officials will address their activities such as the status of their work to evaluate whether the community experiences higher cancer rates. The fire department will be there to speak to questions about chemical safety.

The purpose of the evening community meeting is to:

- Identify and provide answers and information in response to key community questions regarding EtO and what is known and not known about the specific conditions and risks at the Willowbrook Sterigenics facility
- Provide an understanding of agency activities and plans moving forward regarding sampling and evaluation of risks for the Willowbrook community
- Identify a path forward for on-going community information and engagement.

For this event, we would like ATSDR to sit with EPA staff and answer questions as outlined above. There will be no need to prepare a formal presentation.

Attached is a draft agenda for the evening meeting – please note that details will change, but the overall structure should not change much.

I look forward to your response, and please contact me with any questions.

Thank you,

Kelly Rimer

Kelly Rimer  
Leader, Air Toxics Assessment Group  
Health and Environmental Impacts Division  
US EPA  
Office of Air Quality Planning and Standards  
109 TW Alexander Drive  
RTP, NC 27709  
919-541-5368

**From:** [Weinstock, Lewis](#)  
**To:** [Wayland, Richard](#)  
**Cc:** [Hemby, James](#)  
**Subject:** Update on EtO-related Activities for Individual Facilities  
**Date:** Monday, February 11, 2019 12:23:00 PM

---

I'm personally hoping this gets moved.

-----

**Subject:** Update on EtO-related Activities for Individual Facilities

**Location:** WJC - N 5400 + Video with RTP + **Ex. 6 Personal Privacy (PP)**

**Start:** Fri 2/15/2019 4:00 PM

**End:** Fri 2/15/2019 5:00 PM

**Recurrence:** (none)

**Meeting Status:** Accepted

**Organizer:** Wehrum, Bill

**Required Attendees:** Woods, Clint; Mike Koerber ([Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)); Sasser, Erika; Rimer, Kelly; Smith, Darcie; Lassiter, Penny; Witt, Jon; Caparoso, Jennifer; Davis, Alison; Shappley, Ned; Mckelvey, Laura; Rodman, Sonja; Ward, Hillary; Bremer, Kristen; Fruh, Steve; Shine, Brenda; Johnson, Steffan; Wilson, Holly; Weinstock, Lewis; Chen, Xi; Thurman, James; Tsirigotis, Peter; Strum, Madeleine; Jones, Rhea; Hollingsworth, Terri; Long, Pam; Terry, Sara; McBrian, Jenia; Cortelyou-Lee, Jan

**Optional Attendees:** Anderson, Lea; Shoaff, John; Hockstad, Leif; Schwab, Justin; DeLuca, Isabel

**TO:** Bill Wehrum, Clint Woods, Mike Koerber, Erika Sasser, Kelly Rimer, Darcie Smith, Penny Lassiter, Jonathan Witt, Jennifer Caparoso, Alison Davis, Ned Shappley, Laura McKelvey, Sonja Rodman, Hillary Ward, Kristen Bremer, Steve Fruh, Brenda Shine, Steffan Johnson, Holly Wilson, Lewis Weinstock, Xi Chen, James Thurman, Madeleine Strum, Rhea Jones, Terri Hollingsworth, Pam Long, Sara Terry, Jenia McBrian, Jan Cortelyou-Lee

**From:** Koerber, Mike  
**To:** Woods, Clint  
**Cc:** Lewis, Josh  
**Subject:** RE: Live!!  
**Date:** Friday, August 24, 2018 7:17:00 AM

---

Clint: We set up a link on our National EtO website (<https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide>) under Related Links (lower right-hand corner) to [Information for Willowbrook, IL Sterigenics facility](#). All it shows is the data and the ATSDR letter. Once Region 5 prepares a Region 6-like webpage, then we should link to that new website.

---

**From:** Woods, Clint  
**Sent:** Friday, August 24, 2018 10:13 AM  
**To:** Koerber, Mike <Koerber.Mike@epa.gov>  
**Cc:** Lewis, Josh <Lewis.Josh@epa.gov>  
**Subject:** RE: Live!!

Mike,

## Ex. 5 Deliberative Process (DP)

Clint Woods  
Deputy Assistant Administrator  
Office of Air and Radiation, U.S. EPA  
202.564.6562

---

**From:** Koerber, Mike  
**Sent:** Friday, August 24, 2018 9:12 AM  
**To:** Woods, Clint <[woods.clint@epa.gov](mailto:woods.clint@epa.gov)>  
**Cc:** Lewis, Josh <[Lewis.Josh@epa.gov](mailto:Lewis.Josh@epa.gov)>  
**Subject:** RE: Live!!

## Ex. 5 Deliberative Process (DP)

Mike

---

**From:** Koerber, Mike  
**Sent:** Wednesday, August 22, 2018 4:40 PM  
**To:** Woods, Clint <[woods.Clint@epa.gov](mailto:woods.Clint@epa.gov)>  
**Cc:** Lewis, Josh <[Lewis.Josh@epa.gov](mailto:Lewis.Josh@epa.gov)>  
**Subject:** RE: Live!!

FYI – Region 6 has had the following web site in place since the last NATA went out. It has been a valuable source of information for the community.

<https://www.epa.gov/la/laplace-louisiana-health-information>

---

**From:** Woods, Clint  
**Sent:** Wednesday, August 22, 2018 3:04 PM  
**To:** Koerber, Mike <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)>  
**Cc:** Lewis, Josh <[Lewis.Josh@epa.gov](mailto:Lewis.Josh@epa.gov)>  
**Subject:** Re: Live!!

Why does R5 have a stand-alone site?

On Aug 22, 2018, at 3:02 PM, Koerber, Mike <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)> wrote:

In case you haven't heard, the NATA and ethylene oxide web sites went live about an hour ago:

<https://www.epa.gov/national-air-toxics-assessment>

<https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide>

Also, about the same time, Region 5 went live with their Sterigenics web site:

<https://www.epa.gov/il/sterigenics-willowbrook-facility>

Thank you, Clint, with helping to get this done!

Mike

**From:** [Woods, Clint](#)  
**To:** [Jackson, Ryan](#)  
**Cc:** [Konkus, John](#); [Lyons, Troy](#); [Wehrum, Bill](#); [Gunasekara, Mandy](#); [Stepp, Cathy](#); [Thiede, Kurt](#); [Grantham, Nancy](#)  
**Subject:** Re: Draft response to letters  
**Date:** Wednesday, September 26, 2018 2:44:28 PM  
**Attachments:** [EtO Willowbrook response Draft 4..docx](#)  
[ATT00001.htm](#)

---

In case it is helpful (feel free to take or leave pieces if it helps with tone), attached is OAQPS effort to shrink the broader fact sheet into a one pager as discussed this afternoon.

**From:** Weinstock, Lewis  
**To:** McBrian, Jenia  
**Subject:** CONFIDENTIAL & DELIBERATIVE: EtO background  
**Date:** Thursday, October 25, 2018 8:14:00 AM  
**Attachments:** Ethylene Oxide Fact Sheet.Final.8.21.18.pdf

---

Jenia – here is a stream of consciousness sequence of events:

## Ex. 5 Deliberative Process (DP)

Lewis Weinstock | Group Leader | Ambient Air Monitoring Group | Air Quality Assessment Division - Mail Code C304-06 | Office of Air Quality Planning & Standards | U.S. Environmental Protection Agency | Research Triangle Park, NC 27711 | Phone: 919-541-3661|

---

**From:** McBrian, Jenia  
**Sent:** Thursday, October 25, 2018 7:13 AM  
**To:** Weinstock, Lewis <Weinstock.Lewis@epa.gov>  
**Subject:** EtO briefing material

Lew,  
Please provide me with the briefing material on EtO that you presented to Bill Wehrum so I can come up to speed on this project. It would also be helpful if you could provide his response as you outlined it to me so I can share with Jeff.

Thanks,  
Jenia

Jenia McBrian

U.S. Environmental Protection Agency  
Office of Air Quality Planning and Standards  
Central Operations and Resources  
109 T.W. Alexander Dr., Research Triangle Park, NC 27711  
Phone: 919-541-0371

**From:** [Wehrum, Bill](#)  
**To:** [Woods, Clint](#)  
**Subject:** Re: NATA  
**Date:** Sunday, August 19, 2018 6:13:56 AM

---

Thanks.

---

Bill Wehrum  
Assistant Administrator  
Office of Air and Radiation  
U.S. Environmental Protection Agency  
(202) 564-7404

On Aug 19, 2018, at 5:59 AM, Woods, Clint <[woods.clint@epa.gov](mailto:woods.clint@epa.gov)> wrote:

FYI ahead of meeting with Grumbles

Begin forwarded message:

**From:** "Koerber, Mike" <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)>  
**Date:** August 18, 2018 at 11:34:47 AM EDT  
**To:** "Woods, Clint" <[woods.clint@epa.gov](mailto:woods.clint@epa.gov)>  
**Cc:** "Davis, Alison" <[Davis.Alison@epa.gov](mailto:Davis.Alison@epa.gov)>, "Bremer, Kristen" <[Bremer.Kristen@epa.gov](mailto:Bremer.Kristen@epa.gov)>, "Sasser, Erika" <[Sasser.Erika@epa.gov](mailto:Sasser.Erika@epa.gov)>, "Rimer, Kelly" <[Rimer.Kelly@epa.gov](mailto:Rimer.Kelly@epa.gov)>  
**Subject:** Fwd: NATA

## Ex. 5 Deliberative Process (DP)

Mike

Sent from my iPhone

Begin forwarded message:

**From:** George Aburn -MDE-  
<[george.aburn@maryland.gov](mailto:george.aburn@maryland.gov)>  
**Date:** August 17, 2018 at 6:46:07 PM EDT  
**To:** "Koerber, Mike" <[koerber.mike@epa.gov](mailto:koerber.mike@epa.gov)>  
<[koerber.mike@epa.gov](mailto:koerber.mike@epa.gov)>

**Cc:** "[Fernandez.Cristina@epa.gov](mailto:Fernandez.Cristina@epa.gov)"  
<[fernandez.cristina@epa.gov](mailto:fernandez.cristina@epa.gov)>, [chow.alice@epa.gov](mailto:chow.alice@epa.gov)  
**Subject:** NATA

I have my ECOS Air Committee hat on.

Just a heads up. Public release on 8/22 before states have even had a chance to understand analysis is a big problem.

What's the rush. What's driving this?

Seems like a 2 week pause would be a good thing for everybody.

Feel free to call me over the weekend.

Tad

Cell: 443 829 3652

Sent from my iPhone

--

Click here

<<http://www.doit.state.md.us/selectsurvey/TakeSurvey.aspx?agencycode=MDE&SurveyID=86M2956>>

to complete a three question customer experience survey.

**From:** [Woods, Clint](#)  
**To:** [DeLuca, Isabel](#)  
**Cc:** [Wehrum, Bill](#); [Millett, John](#)  
**Subject:** Re: NATA comms  
**Date:** Tuesday, August 21, 2018 3:48:35 PM

---

Isabel,

I will have substantial changes to R5 desk statement, and will send a copy back to you and John. Thanks!

Clint

On Aug 21, 2018, at 6:46 PM, DeLuca, Isabel <[DeLuca.Isabel@epa.gov](mailto:DeLuca.Isabel@epa.gov)> wrote:

Hi Bill and Clint,

The R5 desk statement on Sterigenics is attached for your review. I've also attached the HQ desk statement, NATA fact sheet, and EtO fact sheets – OPA sent these to the regions this afternoon.

Clint— if the R5 desk statement looks ok to you, can you please forward to John Konkus (and cc me so I know it's final too)? John wants to make sure this has cleared OAR IO before he approves.

The plan is to post NATA tomorrow at 2 pm.

Thanks,  
Isabel

**Isabel DeLuca**  
Office of Air and Radiation, US EPA  
(202) 343-9247

<20180821-Sterigenics\_desk\_statement.docx>

<NATA desk statement 8.21.18.docx>

<Ethylene Oxide Fact Sheet.Final.8.21.18.pdf>

<2014 NATA Overview Fact Sheet..pdf>

**From:** [Woods, Clint](#)  
**To:** [DeLuca, Isabel](#)  
**Cc:** [Wehrum, Bill](#); [Millet, John](#)  
**Subject:** Re: In about-face, Gov. Bruce Rauner calls for Sterigenics shutdown after weeks of downplaying cancer risks - Chicago Tribune  
**Date:** Wednesday, October 3, 2018 5:35:24 AM

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Thanks. Updated Willowbrook site is available here, and Kelly R will be taking lead on any additional inquiries from IL officials:

<https://www.epa.gov/il/sterigenics-willowbrook-facility>

On Oct 3, 2018, at 8:32 AM, DeLuca, Isabel <[DeLuca.Isabel@epa.gov](mailto:DeLuca.Isabel@epa.gov)> wrote:

In case you haven't seen this:

<http://www.chicagotribune.com/news/local/breaking/ct-met-bruce-rauner-sterigenics-shutdown-20181002-story.html>

## **In about-face, Gov. Bruce Rauner calls for Sterigenics shutdown after weeks of downplaying cancer risks**

[Michael Hawthorne](#)



After spending the past month downplaying [cancer](#) risks from toxic air pollution in west suburban Willowbrook, Gov. Bruce Rauner on Tuesday joined a chorus of elected officials calling for the shutdown of a Sterigenics International facility co-owned by his former private equity firm.

Fellow Republicans from DuPage County have been clamoring for Rauner to take more aggressive action against the company, which for more than three decades has used highly potent [ethylene oxide gas](#) to sterilize medical instruments, pharmaceutical drugs and food near densely populated neighborhoods and several schools.

As recently as Friday, the most the Republican governor would say about

Sterigenics was that he had instructed the Illinois Environmental Protection Agency to launch an investigation. But Rauner changed course after the weekend, ordered his staff to refer the case to Illinois Attorney General Lisa Madigan, the state's chief lawyer, then urged the Democrat to seek a court order that would close the Willowbrook facility until a separate federal investigation "assures the community that resumed operations would not present an elevated health risk."

Rauner's sudden reversal comes as local politicians, many of whom like the governor are on the Nov. 6 ballot, face a fury of complaints about a federal report that revealed unusually high cancer risks from ethylene oxide pollution in traditionally Republican communities near Sterigenics. Citizen groups that quickly organized against the company garnered even more attention when Burr Ridge resident Andrea Thome and her husband, former Chicago White Sox slugger Jim Thome, added their voices to the anti-Sterigenics movement.

"There is a level of anger in the community that I've never seen before," said longtime state Rep. Jim Durkin of Darien, the House Republican leader and one of several DuPage County officials calling for Sterigenics to be shut down. "This area is populated by young families who are moving here from the city. I know people within a half-mile of the facility who feel they aren't getting any answers and they don't feel anybody is standing up on their behalf."

The Tribune previously reported that quick action is unlikely for a variety of reasons, including steps the Rauner administration took before and after the Willowbrook cancer report was released to the public in late August.

Nearly two months earlier, the Illinois EPA responded to the then-secret report by quietly giving Sterigenics a permit to voluntarily install new pollution-control equipment, making it more difficult for authorities to pursue legal action against the company unless it can be proved that the fix has failed to eliminate health risks from ethylene oxide pollution.

Rauner appointees later refused to provide Madigan's office with key documents about the Willowbrook facility, required the attorney general's staff to request the records under the Freedom of Information Act and delayed providing the information until after the Tribune inquired about the

dispute on Sept. 20. Even now, Madigan said, the state can't make an effective case against Sterigenics without more air quality monitoring in surrounding neighborhoods, expert analysis of the results and other information that only the state or federal EPA can provide.

"We are prepared to move forward in court and have told IEPA what evidence is necessary to shut the site down," Madigan said. "IEPA has not provided any evidence, but we will immediately evaluate any information the agency provides."

With Election Day just a few weeks away, locally elected officials have repeatedly urged state and federal regulators to reassure the public they are safe. Rauner, along with top Trump administration officials at the U.S. Environmental Protection Agency, have stressed that there is no evidence Sterigenics poses the type of immediate threats seen in some work settings. But the company has been releasing ethylene oxide into surrounding communities since the early 1980s, federal records show, and the health risks involve diseases that can take years to develop, including breast cancer, leukemia and lymphoma.

Based on air samples collected in May, an arm of the federal Centers for Disease Control and Prevention determined the cancer risks from breathing ethylene oxide pollution in southeast DuPage communities could be orders of magnitude higher than initially estimated: up to 6,400 per million, or more than six cases of cancer for every 1,000 people. The U.S. EPA generally targets polluters when local cancer risks exceed 100 in a million.

The pre-election political stakes are high enough that the Trump administration weighed in on the issue last week, dispatching a presidential appointee in charge of the EPA's air division to promise the agency will conduct the type of neighborhood air monitoring that Madigan and others have been calling for during the past month.

Sterigenics said a controlled test of emissions, conducted in late September by consultants hired by the company, failed to detect any ethylene oxide leaving its pair of buildings in Willowbrook.

"We are committed to doing the right thing by our community but closing facilities that emit limited, regulated (ethylene oxide) emissions is not the right answer," the company said in a statement, calling Rauner's latest

reaction “ill-considered.” “If necessary, we will take all appropriate actions to protect the hospitals and patients that depend on our facility.”

Rauner’s ties to the company date to 2011, when a private equity firm he co-founded bought Sterigenics for \$675 million and quickly expanded its operations. The governor’s most recent state ethics statement, filed in May, shows he retains an interest in the fund used to buy the sterilization company, which in 2015 sold a majority stake to another private equity firm.

On Friday morning, Rauner told radio station WBEZ he no longer has a stake in Sterigenics. Spokespeople for his campaign and government office later told the Tribune that Rauner sold his interest as part of the 2015 deal but have not produced documents showing the transaction took place.

“We will get the truth about what has been emitted so far,” Rauner told the radio station, “and what needs to change in the future.”

[mhawthorne@chicagotribune.com](mailto:mhawthorne@chicagotribune.com)

Twitter [@scribeguy](#)

## **MORE COVERAGE**

[After weeks of public outrage about Sterigenics, Trump EPA to test air in surrounding neighborhoods »](#)

[Rauner EPA withholds Sterigenics records from attorney general until local Republicans intervene »](#)

[High cancer risk in southeast DuPage County linked to company co-owned by Rauner’s former firm »](#)

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**Jeff Kelley**

Director, Office of External Communications

U.S. EPA Region 5

ph: 312-353-1159

**From:** [DeLuca, Isabel](#)  
**To:** [Wehrum, Bill](#); [Woods, Clint](#)  
**Cc:** [Millet, John](#)  
**Subject:** NATA comms  
**Date:** Tuesday, August 21, 2018 3:46:12 PM  
**Attachments:** [20180821-Sterigenics\\_desk\\_statement.docx](#)  
[NATA\\_desk\\_statement\\_8.21.18.docx](#)  
[Ethylene Oxide Fact Sheet.Final.8.21.18.pdf](#)  
[2014 NATA Overview Fact Sheet..pdf](#)

---

Hi Bill and Clint,

The R5 desk statement on Sterigenics is attached for your review. I've also attached the HQ desk statement, NATA fact sheet, and EtO fact sheets – OPA sent these to the regions this afternoon.

Clint— if the R5 desk statement looks ok to you, can you please forward to John Konkus (and cc me so I know it's final too)? John wants to make sure this has cleared OAR IO before he approves.

The plan is to post NATA tomorrow at 2 pm.

Thanks,  
Isabel

**Isabel DeLuca**

Office of Air and Radiation, US EPA  
(202) 343-9247

**From:** Weinstock, Lewis  
**To:** McBrian, Jenia  
**Subject:** RE: EtO briefing material  
**Date:** Thursday, October 25, 2018 7:22:00 AM  
**Attachments:** Sampling Plan - EtO - Sterigenics Willowbrook - Rev 10-18-18.docx

---

Hi Jenia:

Bill doesn't like paper so the discussion was mainly a verbal exchange about the proposed monitoring plan, which I have attached here. After this discussion, we were directed to shorten the duration of the monitoring from six months to three months, which is reflected in the current wording. There will likely be further changes as we discuss the plan with local political leaders and community groups. Those changes are very likely to be the addition of sites, perhaps from six to eight.

Lewis Weinstock | Group Leader | Ambient Air Monitoring Group | Air Quality Assessment Division - Mail Code C304-06 | Office of Air Quality Planning & Standards | U.S. Environmental Protection Agency | Research Triangle Park, NC 27711 | Phone: 919-541-3661|

---

**From:** McBrian, Jenia  
**Sent:** Thursday, October 25, 2018 7:13 AM  
**To:** Weinstock, Lewis <Weinstock.Lewis@epa.gov>  
**Subject:** EtO briefing material

Lew,

Please provide me with the briefing material on EtO that you presented to Bill Wehrum so I can come up to speed on this project. It would also be helpful if you could provide his response as you outlined it to me so I can share with Jeff.

Thanks,

Jenia


Jenia McBrian  
U.S. Environmental Protection Agency  
Office of Air Quality Planning and Standards  
Central Operations and Resources  
109 T.W. Alexander Dr., Research Triangle Park, NC 27711  
Phone: 919-541-0371

## Mahgoub, Gaida

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**From:** Smith, Darcie  
**Sent:** Tuesday, August 28, 2018 3:42 PM  
**To:** Rimer, Kelly  
**Subject:** RE: DRAFT NATA data request response plan KR 08 28 18.docx  
**Attachments:** DRAFT NATA data request response plan KR 08 28 18\_dps.docx

Back atcha

Darcie Smith  
U.S. EPA/OAQPS/ ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Rimer, Kelly  
**Sent:** Tuesday, August 28, 2018 10:26 AM  
**To:** Smith, Darcie <Smith.Darcie@epa.gov>  
**Subject:** DRAFT NATA data request response plan KR 08 28 18.docx

This looks good. Please see my comments.

I removed the disadvantage from the pager, but will use it if necessary when talking to SPPD

Thanks,  
Kelly


## Mahgoub, Gaida

---

**From:** Smith, Darcie  
**Sent:** Thursday, August 30, 2018 8:39 AM  
**To:** Rimer, Kelly;Truesdell, Raymond  
**Subject:** RE: 9/7 stakeholder meeting

I haven't heard of it either. Ex. 5 Deliberative Process (DP)

If it is for NATA, we should totally be involved.

Darcie Smith  
U.S. EPA/OAQPS/ ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Rimer, Kelly  
**Sent:** Thursday, August 30, 2018 8:14 AM  
**To:** Truesdell, Raymond <[truesdell.raymond@epa.gov](mailto:truesdell.raymond@epa.gov)>  
**Cc:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Subject:** RE: 9/7 stakeholder meeting

Rod,  
Do we have any information about the call?  
Im not aware of it.

And yes, it would be great if you would help KB

---

**From:** Truesdell, Raymond  
**Sent:** Wednesday, August 29, 2018 4:16 PM  
**To:** Rimer, Kelly <[Rimer.Kelly@epa.gov](mailto:Rimer.Kelly@epa.gov)>  
**Cc:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Subject:** FW: 9/7 stakeholder meeting

FYI. KB has asked for my help to work on a NATA script for their upcoming stakeholder call/meeting. Let me know if you have any comments.

---

**From:** Mills, Kathy  
**Sent:** Wednesday, August 29, 2018 3:54 PM  
**To:** Cortelyou-Lee, Jan <[Cortelyou-Lee.Jan@epa.gov](mailto:Cortelyou-Lee.Jan@epa.gov)>  
**Cc:** Truesdell, Raymond <[truesdell.raymond@epa.gov](mailto:truesdell.raymond@epa.gov)>  
**Subject:** 9/7 stakeholder meeting

Jan,  
As we just discussed, here are some samples from previous stakeholder meetings.

Rod,

We can work together to craft NATA script – I'll provide EtO bullets. This will be for 9/7 meeting. Let's talk tomorrow if your time allows?

KB

Kathy "KB Mills ~ SPPD ~ U. S. EPA, OAQPS ~ 919-541-1599


## Mahgoub, Gaida

---

**From:** Smith, Darcie  
**Sent:** Thursday, August 30, 2018 10:33 AM  
**To:** Truesdell, Raymond; Lamason, Bill; Torres, Elineth; Godfrey, Janice; Howard, Jodi; Shrager, Brian; Dalcher, Debra; Schaefer, John; Goehl, Eric; Perry, Nancy  
**Subject:** RE: PSG Staff Meeting -at 9 am today!! HEID coming!

I'm sure this goes without saying, but these are for your internal use only and should not be shared.

Thanks!

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Truesdell, Raymond  
**Sent:** Thursday, August 30, 2018 10:25 AM  
**To:** Lamason, Bill <[Lamason.Bill@epa.gov](mailto:Lamason.Bill@epa.gov)>; Torres, Elineth <[Torres.Elineth@epa.gov](mailto:Torres.Elineth@epa.gov)>; Godfrey, Janice <[Godfrey.Janice@epa.gov](mailto:Godfrey.Janice@epa.gov)>; Howard, Jodi <[Howard.Jodi@epa.gov](mailto:Howard.Jodi@epa.gov)>; Shrager, Brian <[Shrager.Brian@epa.gov](mailto:Shrager.Brian@epa.gov)>; Dalcher, Debra <[dalcher.debra@epa.gov](mailto:dalcher.debra@epa.gov)>; Schaefer, John <[Schaefer.John@epa.gov](mailto:Schaefer.John@epa.gov)>; Goehl, Eric <[Goehl.Eric@epa.gov](mailto:Goehl.Eric@epa.gov)>; Perry, Nancy <[Perry.Nancy@epa.gov](mailto:Perry.Nancy@epa.gov)>  
**Cc:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Subject:** RE: PSG Staff Meeting -at 9 am today!! HEID coming!

Hi folks,

Thanks again for being such a great audience today! It was a lot of fun. Here are the slides from the NATA presentation. Please let Darcie or me know if you have any other questions.

Thanks,

Rod Truesdell

---

**From:** Lamason, Bill  
**Sent:** Thursday, August 30, 2018 8:47 AM  
**To:** Torres, Elineth <[Torres.Elineth@epa.gov](mailto:Torres.Elineth@epa.gov)>; Godfrey, Janice <[Godfrey.Janice@epa.gov](mailto:Godfrey.Janice@epa.gov)>; Howard, Jodi <[Howard.Jodi@epa.gov](mailto:Howard.Jodi@epa.gov)>; Shrager, Brian <[Shrager.Brian@epa.gov](mailto:Shrager.Brian@epa.gov)>; Dalcher, Debra <[dalcher.debra@epa.gov](mailto:dalcher.debra@epa.gov)>; Schaefer, John <[Schaefer.John@epa.gov](mailto:Schaefer.John@epa.gov)>; Goehl, Eric <[Goehl.Eric@epa.gov](mailto:Goehl.Eric@epa.gov)>; RTP-OAQPS-919-541-4332-SPPD/Phone-Line/RTP-OAQPS-BLDG-C <[RTP-OAQPS-919-541-4332-SPPD@epa.gov](mailto:RTP-OAQPS-919-541-4332-SPPD@epa.gov)>; Perry, Nancy <[Perry.Nancy@epa.gov](mailto:Perry.Nancy@epa.gov)>; Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>; Truesdell, Raymond <[truesdell.raymond@epa.gov](mailto:truesdell.raymond@epa.gov)>  
**Subject:** PSG Staff Meeting -at 9 am today!! HEID coming!


## Mahgoub, Gaida

---

**From:** Smith, Darcie  
**Sent:** Monday, September 17, 2018 8:42 AM  
**To:** Kelly Rimer  
**Subject:** FW: EtO action items

Re #2, would you like to let Mike know that the mtg with ATSDR is scheduled for Thurs 10 am our time, with a pre-mtg on Wed at 2:30 pm our time. He should be on the Thurs mtg already – Margaret was going to add him. But if not, we can forward it to him.

As for sharing results, this will be a great thing to discuss Tues am when Madeleine and Jennifer are also present.

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Koerber, Mike  
**Sent:** Friday, September 14, 2018 10:31 AM  
**To:** Caparoso, Jennifer <Caparoso.Jennifer@epa.gov>; Lassiter, Penny <Lassiter.Penny@epa.gov>; Rimer, Kelly <Rimer.Kelly@epa.gov>; Smith, Darcie <Smith.Darcie@epa.gov>; Shappley, Ned <Shappley.Ned@epa.gov>; Davis, Alison <Davis.Alison@epa.gov>; Cortelyou-Lee, Jan <Cortelyou-Lee.Jan@epa.gov>  
**Cc:** Sasser, Erika <Sasser.Erika@epa.gov>; Cozzie, David <Cozzie.David@epa.gov>; Wayland, Richard <Wayland.Richard@epa.gov>  
**Subject:** EtO action items

After talking with Clint yesterday, he's asked that we do the following:

- Set-up meeting/phone call between OAR and Sterigenics. Please reach out the appropriate person in Sterigenics, such as Kathy Hoffman – or do you have another contact? It would be good to have this meeting next week, if possible.
- Set-up meeting/phone call between OAR and ATSDR. This should be with folks at the ATSDR Headquarters level. This meeting, too, would be good to have next week, if possible.
- Begin to get ready for the small meeting with elected officials in Chicago, which will possibly be next week. For example, let's draft our plan for what we want to discuss and appropriate messaging. Also, Clint just received a draft pager from ORD on their IRIS assessment, which he will share with us. He's considering whether ORD should be part of this meeting, but will need to identify an appropriate ORD POC.

Also, I talked with him about fugitives monitoring for Solvay and sharing NATA modeling results in response to requests from Regions and states. I will call Beverly to discuss the Solvay situation. With respect to sharing modeling results, he's generally okay with doing so, but wanted to be sure that it's consistent with past practice or information shared during the preview period. It might be good to talk first before we actually send anything out.

Please let me know if you have questions about any of this.

Mike


**Mahgoub, Gaida**

---

**From:** Smith, Darcie  
**Sent:** Thursday, September 27, 2018 4:58 PM  
**To:** Kelly Rimer  
**Subject:** thoughts on modeling

# Ex. 5 Deliberative Process (DP)

Happy to provide additional details if needed.


Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

## Mahgoub, Gaida

---

**From:** Smith, Darcie  
**Sent:** Monday, October 1, 2018 4:13 PM  
**To:** Palma, Ted (Palma.Ted@epa.gov); Morris, Mark; Woody, Matthew; Strum, Madeleine; Eyth, Alison; Thurman, James; Phillips, Sharon; Myers, Jeff D - DNR; Chow, Alice; Sieffert, Margaret; Cook, Rich  
**Subject:** Additional articles/letters  
**Attachments:** New cancer-causing danger in Baton Rouge-New Orleans corridor, EPA report says \_ News \_ theadvocate.com.pdf; RFC 18003 Request.pdf

Here's an article about EtO in Louisiana and ACC's letter to request a correction to the IRIS value.

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

**From:** Diem, Art  
**Sent:** Wednesday, June 20, 2018 2:03 PM  
**To:** Shelow, David;Rimer, Kelly;Smith, Darcie;Koerber, Mike;Vandenberg, John;Palma, Ted;Wayland, Richard;Hemby, James;Noonan, Jenny;Strum, Madeleine;Verhalen, Frances;Shappley, Ned;Lowe, Theresa;Leathers, James;Lassiter, Penny;Srivastava, Ravi;Price, Lisa;Stenger, Wren;Oyedapo, Deborah;Bremer, Kristen;Lutz, Craig;Weinstock, Lewis;Stewart, Michael;Johnson, Steffan;Madden, Joshua;Hoyt, Daniel;Osbourne, Margaret;Donaldson, Guy;Shine, Brenda;Langdon, Robin;Imhoff, Robert  
**Subject:** draft chloroprene charts/map

FYI. Please see attached draft displays of ambient data through June 3, 2018.

\* Two full years of ambient data! \*

## Ex. 5 Deliberative Process (DP)

# **Ex. 5 Deliberative Process (DP)**

# Ex. 5 Deliberative Process (DP)

Thanks,  
Art

.....  
Art Diem, Environmental Engineer

USEPA Office of Air Quality Planning and Standards,  
Sector Policies and Programs Division,  
Refining and Chemicals Group  
[Dien.Art@epa.gov](mailto:Dien.Art@epa.gov)  
919-541-1185

## Mahgoub, Gaida

---

**From:** Smith, Darcie  
**Sent:** Tuesday, October 2, 2018 5:58 PM  
**To:** Strum, Madeleine; Thurman, James; Shappley, Ned; Woody, Matthew; Sieffert, Margaret  
**Cc:** Morris, Mark  
**Subject:** Sterigenics Modeling



Hi –

If I've done this correctly, you should now all be able to access the modeling files provided today by Sterigenics. Mark is working through them, but I wanted you to have access too. (If I haven't done it correctly, well, I'm sure you'll let me know...)

In [this folder](#) you should see the met data (surface and profile files for 2012-2016 for Midway), the aermod.inp file, and an excel file with their modeling inputs. When we get results, we'll post them here to for review, QA, etc.

Ned – as you gain updated information from the stack test, we can add columns to the excel sheet with the revised information.

Thanks,  
Darcie

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
 919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

**Mahgoub, Gaida**


---

**From:** Smith, Darcie  
**Sent:** Monday, September 24, 2018 10:01 AM  
**To:** Jones, DonnaLee;Truesdell, Raymond  
**Subject:** RE: SPPD All-Hands Meeting - MIR for coke facility/census block in PA

Hi Donna –

## Ex. 5 Deliberative Process (DP)

Thanks,  
Darcie

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Jones, DonnaLee  
**Sent:** Friday, September 21, 2018 3:53 PM  
**To:** Truesdell, Raymond <truesdell.raymond@epa.gov>  
**Cc:** Smith, Darcie <Smith.Darcie@epa.gov>  
**Subject:** RE: SPPD All-Hands Meeting - MIR for coke facility/census block in PA

## Ex. 5 Deliberative Process (DP)

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Regards,  
Donna Lee Jones, Ph.D.  
Senior Technical Advisor, Metals Sector  
U. S. Environmental Protection Agency  
Office of Air Quality Planning and Standards  
Sector Policies and Programs Division / Metals & Inorganic Chemicals Group (D 243-02)  
Research Triangle Park, NC 27711 Tele: (919) 541-5251 Fax (919) 541-3207

"Reasonableness never fails to be appreciated." - anon.

---

**From:** Truesdell, Raymond  
**Sent:** Friday, September 21, 2018 3:16 PM  
**To:** Jones, DonnaLee <Jones.Donnalee@epa.gov>

Cc: Smith, Darcie <Smith.Darcie@epa.gov>

Subject: RE: SPPD All-Hands Meeting - MIR for coke facility/census block in PA

You're welcome!

## Ex. 5 Deliberative Process (DP)

Thanks again,

Rod

---

From: Jones, DonnaLee

Sent: Friday, September 21, 2018 2:57 PM

To: Truesdell, Raymond <truesdell.raymond@epa.gov>

Cc: Smith, Darcie <Smith.Darcie@epa.gov>

Subject: RE: SPPD All-Hands Meeting - MIR for coke facility/census block in PA

## Ex. 5 Deliberative Process (DP)

---

Regards,

Donna Lee Jones, Ph.D.

Senior Technical Advisor, Metals Sector

U. S. Environmental Protection Agency

Office of Air Quality Planning and Standards

Sector Policies and Programs Division / Metals & Inorganic Chemicals Group (D 243-02)

Research Triangle Park, NC 27711 Tele: (919) 541-5251 Fax: (919) 541-3207

---

"Reasonableness never fails to be appreciated." - anon.

---

From: Truesdell, Raymond

Sent: Friday, September 21, 2018 2:52 PM

To: Jones, DonnaLee <Jones.DonnaLee@epa.gov>; Joseph, Wanda <joseph.wanda@epa.gov>

Cc: Smith, Darcie <Smith.Darcie@epa.gov>

Subject: RE: SPPD All-Hands Meeting - MIR for coke facility/census block in PA

Hi Donna,

I'm attaching a PDF of the presentation; thanks for your interest.

## Ex. 5 Deliberative Process (DP)

If you would like to visit the [NATA website](#), you can use the [NATA Map app](#) to do a search for any area you wish, including the elevated risk areas near Pittsburgh. Clicking on the map will give you the census tract information.

I hope that helps! Please let me know if you have any other questions.

Raymond "Rod" Truesdell  
Physical Scientist  
U.S. EPA/OAQPS/ATAG  
919-541-5615

---

**From:** Jones, DonnaLee  
**Sent:** Friday, September 21, 2018 2:23 PM  
**To:** Joseph, Wanda <[joseph.wanda@epa.gov](mailto:joseph.wanda@epa.gov)>  
**Cc:** Truesdell, Raymond <[truesdell.raymond@epa.gov](mailto:truesdell.raymond@epa.gov)>; Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Subject:** RE: SPPD All-Hands Meeting - MIR for coke facility/census block in PA

## Ex. 5 Deliberative Process (DP)

---

Regards,  
Donna Lee Jones, Ph.D.  
Senior Technical Advisor, Metals Sector  
U. S. Environmental Protection Agency  
Office of Air Quality Planning and Standards  
Sector Policies and Programs Division / Metals & Inorganic Chemicals Group (D 243-02)  
Research Triangle Park, NC 27711 Tele: (919) 541-5251 Fax (919) 541-3207  
\*\*\*\*\*

"Reasonableness never fails to be appreciated." - anon.

---

**From:** Joseph, Wanda  
**Sent:** Friday, September 21, 2018 2:07 PM  
**To:** Jones, DonnaLee <[jones.donnalee@epa.gov](mailto:jones.donnalee@epa.gov)>  
**Cc:** Truesdell, Raymond <[truesdell.raymond@epa.gov](mailto:truesdell.raymond@epa.gov)>; Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Subject:** RE: SPPD All-Hands Meeting

Donna,

I don't have a copy of the presentation, I believe it was Raymond Truesdell that gave the presentation with Darcie. I am cc'ing him and Darcie on this. I am sure they will be happy to provide you with a copy.

V/r

*Wanda Joseph*

Administrative Specialist  
Sector Policies and Programs Division  
Office of Air Quality Planning and Standards  
109 T.W. Alexander Drive, MC: C504-04  
Research Triangle Park, NC 27711  
(919) 541-3114

---

**From:** Jones, DonnaLee  
**Sent:** Friday, September 21, 2018 1:47 PM  
**To:** Joseph, Wanda <joseph.wanda@epa.gov>  
**Subject:** RE: SPPD All-Hands Meeting

Hi Wanda - Do you happen to have an electronic copy of the NATA presentation I could have? Alternatively, do you know the name of the person (male) who presented with Darcie?

---

Regards,  
Donna Lee Jones, Ph.D.  
Senior Technical Advisor, Metals Sector  
U. S. Environmental Protection Agency  
Office of Air Quality Planning and Standards  
Sector Policies and Programs Division / Metals & Inorganic Chemicals Group (D 243-02)  
Research Triangle Park, NC 27711 Tele: (919) 541-5251 Fax (919) 541-3207

"Reasonableness never fails to be appreciated." - anon.

---

**From:** Joseph, Wanda  
**Sent:** Thursday, September 20, 2018 9:15 AM  
**To:** OAQPS SPPD <OAQPS\_SPPD@epa.gov>; Smith, Darcie <Smith.Darcie@epa.gov>  
**Subject:** SPPD All-Hands Meeting

Good Morning everyone,

I apologize for the confusion. The SPPD-ALL Hands Meeting is still being held at 2pm-3:30pm. I inadvertently cancelled instead of updating the meeting. I have attached a copy of the agenda to this email.

V/r  
*Wanda Joseph*  
Administrative Specialist  
Sector Policies and Programs Division  
Office of Air Quality Planning and Standards  
109 T.W. Alexander Drive, MC: C504-04  
Research Triangle Park, NC 27711  
(919) 541-3114

## Mahgoub, Gaida

---

**From:** Smith, Darcie  
**Sent:** Wednesday, September 12, 2018 4:16 PM  
**To:** Catherine Gaertner; Jill Mozier  
**Subject:** RE: Posting OLD MACT Actual facility folders now

Thank you ☺

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
📞 919.541.2076  
✉ [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Catherine Gaertner [<mailto:cgaertner@scainc.com>]  
**Sent:** Wednesday, September 12, 2018 3:53 PM  
**To:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>; Jill Mozier <[jmozier@scainc.com](mailto:jmozier@scainc.com)>  
**Subject:** RE: Posting OLD MACT Actual facility folders now

Darcie,

Here's the source location kmz file. You can turn off the census blocks by unchecking the box on the left.

Catherine

---

**From:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Sent:** Wednesday, September 12, 2018 3:46 PM  
**To:** Catherine Gaertner <[cgaertner@scainc.com](mailto:cgaertner@scainc.com)>; Jill Mozier <[jmozier@scainc.com](mailto:jmozier@scainc.com)>  
**Subject:** RE: Posting OLD MACT Actual facility folders now

Wow – that's quite significant. Can you please send me the kmz without the risk results in it i.e., just the sources? Thanks!

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
📞 919.541.2076  
✉ [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Catherine Gaertner [<mailto:cgaertner@scainc.com>]  
**Sent:** Wednesday, September 12, 2018 1:40 PM  
**To:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>; Jill Mozier <[jmozier@scainc.com](mailto:jmozier@scainc.com)>  
**Subject:** RE: Posting OLD MACT Actual facility folders now

Darcie,


# Ex. 5 Deliberative Process (DP)

Catherine

---

**From:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Sent:** Wednesday, September 12, 2018 1:24 PM  
**To:** Catherine Gaertner <[cgaertner@scainc.com](mailto:cgaertner@scainc.com)>; Jill Mozier <[jmozier@scainc.com](mailto:jmozier@scainc.com)>  
**Subject:** RE: Posting OLD MACT Actual facility folders now

Yes please.

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Catherine Gaertner [<mailto:cgaertner@scainc.com>]  
**Sent:** Wednesday, September 12, 2018 1:24 PM  
**To:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>; Jill Mozier <[jmozier@scainc.com](mailto:jmozier@scainc.com)>  
**Subject:** RE: Posting OLD MACT Actual facility folders now


# Ex. 5 Deliberative Process (DP)

Catherine

---

**From:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Sent:** Wednesday, September 12, 2018 12:55 PM  
**To:** Catherine Gaertner <[cgaertner@scainc.com](mailto:cgaertner@scainc.com)>; Jill Mozier <[jmozier@scainc.com](mailto:jmozier@scainc.com)>  
**Subject:** RE: Posting OLD MACT Actual facility folders now

What about the third?

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Catherine Gaertner [<mailto:cgaertner@scainc.com>]  
**Sent:** Wednesday, September 12, 2018 12:43 PM

**To:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>; Jill Mozier <[jmozier@scainc.com](mailto:jmozier@scainc.com)>

**Subject:** RE: Posting OLD MACT Actual facility folders now

Darcie,

# Ex. 5 Deliberative Process (DP)

I'll continue with my QA run and let you know the results. Let me know if you decide to make any other changes.

Catherine

984-234-3966

[cgaertner@scainc.com](mailto:cgaertner@scainc.com)



---

**From:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>

**Sent:** Tuesday, September 11, 2018 4:38 PM

**To:** Jill Mozier <[jmozier@scainc.com](mailto:jmozier@scainc.com)>

**Cc:** Catherine Gaertner <[cgaertner@scainc.com](mailto:cgaertner@scainc.com)>

**Subject:** RE: Posting OLD MACT Actual facility folders now

Yes, that is correct – SC will have fewer. Chris did send one – let me find it.

Thx!

Darcie Smith

U.S. EPA/OAQPS/ATAG

919.541.2076

[smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Jill Mozier [<mailto:jmozier@scainc.com>]

**Sent:** Tuesday, September 11, 2018 4:23 PM

**To:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>

**Cc:** Catherine Gaertner <[cgaertner@scainc.com](mailto:cgaertner@scainc.com)>

**Subject:** RE: Posting OLD MACT Actual facility folders now

Hey Darcie,

# Ex. 5 Deliberative Process (DP)

Thank you,  
Jill

Jill Mozier  
(984) 234-3968  
[jmozier@scainc.com](mailto:jmozier@scainc.com)

---

**From:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Sent:** Tuesday, September 11, 2018 4:08 PM  
**To:** Jill Mozier <[jmozier@scainc.com](mailto:jmozier@scainc.com)>  
**Cc:** Catherine Gaertner <[cgaertner@scainc.com](mailto:cgaertner@scainc.com)>  
**Subject:** RE: Posting OLD MACT Actual facility folders now

Hey there –

# Ex. 5 Deliberative Process (DP)

Thanks,  
Darcie

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
📞 919.541.2076  
✉️ [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Jill Mozier [<mailto:jmozier@scainc.com>]  
**Sent:** Monday, September 10, 2018 5:03 PM  
**To:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>; Holder, Chris <[Chris.Holder@icf.com](mailto:Chris.Holder@icf.com)>  
**Cc:** Catherine Gaertner <[cgaertner@scainc.com](mailto:cgaertner@scainc.com)>  
**Subject:** RE: Posting OLD MACT Actual facility folders now

Thanks for letting us know, Darcie.

# Ex. 5 Deliberative Process (DP)

Jill Mozier  
(984) 234-3968  
[jmozier@scainc.com](mailto:jmozier@scainc.com)


---

**From:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Sent:** Monday, September 10, 2018 4:57 PM  
**To:** Jill Mozier <[jmozier@scainc.com](mailto:jmozier@scainc.com)>; Holder, Chris <[Chris.Holder@icf.com](mailto:Chris.Holder@icf.com)>  
**Subject:** RE: Posting OLD MACT Actual facility folders now

Hey you guys –

## Ex. 5 Deliberative Process (DP)

Thanks,  
Darcie

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Jill Mozier [<mailto:jmozier@scainc.com>]  
**Sent:** Thursday, September 06, 2018 6:02 PM  
**To:** Holder, Chris <[Chris.Holder@icf.com](mailto:Chris.Holder@icf.com)>  
**Cc:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Subject:** Posting OLD MACT Actual facility folders now

Chris,

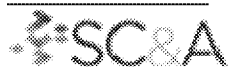
## Ex. 5 Deliberative Process (DP)

They may take 45 minutes or so to post, however.

Thanks,  
Jill

---

Jill Mozier  
Environmental Engineer  
(984) 234-3968  
Chapel Hill, North Carolina  
[jmozier@scainc.com](mailto:jmozier@scainc.com)  
[www.scainc.com](http://www.scainc.com)



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## Mahgoub, Gaida

---

**From:** Smith, Darcie  
**Sent:** Wednesday, October 3, 2018 10:23 AM  
**To:** Shappley, Ned; Sasser, Erika; Riha, Kristin; Jones, Rhea; Rimer, Kelly; Davis, Alison; Bremer, Kristen  
**Subject:** RE: Use this version! RE: DRAFT FOR REVIEW - DDL noon Wednesday - Pager for Acting Administrator  
**Attachments:** Eto and Willowbrook.Briefing paper for Administrator. DRAFT v2\_ensNS\_dps.docx

Here's my 2 cents. I tried to address Erika's comments. Let me know if you need more.

Thanks,  
Darcie

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Shappley, Ned  
**Sent:** Wednesday, October 03, 2018 9:38 AM  
**To:** Sasser, Erika <[Sasser.Erika@epa.gov](mailto:Sasser.Erika@epa.gov)>; Riha, Kristin <[Riha.Kristin@epa.gov](mailto:Riha.Kristin@epa.gov)>; Jones, Rhea <[Jones.Rhea@epa.gov](mailto:Jones.Rhea@epa.gov)>; Rimer, Kelly <[Rimer.Kelly@epa.gov](mailto:Rimer.Kelly@epa.gov)>; Davis, Alison <[Davis.Alison@epa.gov](mailto:Davis.Alison@epa.gov)>; Bremer, Kristen <[Bremer.Kristen@epa.gov](mailto:Bremer.Kristen@epa.gov)>; Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Subject:** RE: Use this version! RE: DRAFT FOR REVIEW - DDL noon Wednesday - Pager for Acting Administrator

A couple of suggested revisions on my end.

Thanks!

---

**From:** Sasser, Erika  
**Sent:** Wednesday, 3 October, 2018 08:29  
**To:** Riha, Kristin <[Riha.Kristin@epa.gov](mailto:Riha.Kristin@epa.gov)>; Jones, Rhea <[Jones.Rhea@epa.gov](mailto:Jones.Rhea@epa.gov)>; Rimer, Kelly <[Rimer.Kelly@epa.gov](mailto:Rimer.Kelly@epa.gov)>; Davis, Alison <[Davis.Alison@epa.gov](mailto:Davis.Alison@epa.gov)>; Bremer, Kristen <[Bremer.Kristen@epa.gov](mailto:Bremer.Kristen@epa.gov)>; Shappley, Ned <[Shappley.Ned@epa.gov](mailto:Shappley.Ned@epa.gov)>; Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Subject:** RE: Use this version! RE: DRAFT FOR REVIEW - DDL noon Wednesday - Pager for Acting Administrator

Looks good. A few thoughts. Thx

---

**From:** Riha, Kristin  
**Sent:** Wednesday, October 03, 2018 7:16 AM  
**To:** Jones, Rhea <[Jones.Rhea@epa.gov](mailto:Jones.Rhea@epa.gov)>; Sasser, Erika <[Sasser.Erika@epa.gov](mailto:Sasser.Erika@epa.gov)>  
**Subject:** Fw: Use this version! RE: DRAFT FOR REVIEW - DDL noon Wednesday - Pager for Acting Administrator

---

Hi Erika and Rhea, FYI!

**From:** Davis, Alison

**Sent:** Tuesday, October 2, 2018 10:25 PM

**To:** Rimer, Kelly; Koerber, Mike; Bremer, Kristen; Shappley, Ned

**Cc:** Riha, Kristin; Smith, Darcie

**Subject:** Use this version! RE: DRAFT FOR REVIEW - DDL noon Wednesday - Pager for Acting Administrator

All,

When I went to look at Kelly's edits, I realized that I had forgotten to turn track changes off (I'd been working off Clint's document) with the markup turned off. Here's a clean version to review.

Kelly – I couldn't actually *find* your edits amid all of the redline in the previous version (sorry about that). If you'll send or otherwise flag, I'll transfer to this version. Let's talk about the community expectations and what you'd like to add.

Thanks!

Alison

---

**From:** Rimer, Kelly

**Sent:** Tuesday, October 02, 2018 8:50 PM

**To:** Davis, Alison <[Davis.Alison@epa.gov](mailto:Davis.Alison@epa.gov)>; Koerber, Mike <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)>; Bremer, Kristen <[Bremer.Kristen@epa.gov](mailto:Bremer.Kristen@epa.gov)>; Shappley, Ned <[Shappley.Ned@epa.gov](mailto:Shappley.Ned@epa.gov)>

**Cc:** Riha, Kristin <[Riha.Kristin@epa.gov](mailto:Riha.Kristin@epa.gov)>; Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>

**Subject:** RE: DRAFT FOR REVIEW - DDL noon Wednesday - Pager for Acting Administrator

A few comments on the general pager

Do we want to add the communities expectations?

Kelly

---

**From:** Davis, Alison

**Sent:** Tuesday, October 02, 2018 6:12 PM

**To:** Koerber, Mike <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)>; Rimer, Kelly <[Rimer.Kelly@epa.gov](mailto:Rimer.Kelly@epa.gov)>; Bremer, Kristen <[Bremer.Kristen@epa.gov](mailto:Bremer.Kristen@epa.gov)>; Shappley, Ned <[Shappley.Ned@epa.gov](mailto:Shappley.Ned@epa.gov)>

**Cc:** Riha, Kristin <[Riha.Kristin@epa.gov](mailto:Riha.Kristin@epa.gov)>

**Subject:** DRAFT FOR REVIEW - DDL noon Wednesday - Pager for Acting Administrator

All, attached is a draft "pager" for Acting Administrator Wheeler providing an update on EtO & Willowbrook. Please review and get comments to me by noon tomorrow. Feel free to loop others as needed.

Kelly/Ned – see highlighted areas

Thanks.



**Mahgoub, Gaida**

---

**From:** Smith, Darcie  
**Sent:** Wednesday, October 3, 2018 11:22 AM  
**To:** Palma, Ted  
**Cc:** Morris, Mark  
**Subject:** RE: Proposed data dissemination plan - draft

## Ex. 5 Deliberative Process (DP)

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
[smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Palma, Ted  
**Sent:** Tuesday, October 02, 2018 9:40 AM  
**To:** Smith, Darcie <Smith.Darcie@epa.gov>  
**Cc:** Morris, Mark <Morris.Mark@epa.gov>  
**Subject:** Re: Proposed data dissemination plan - draft

I don't know the context of Maddie's email, who is this for?

Ex. 5 Deliberative Process (DP)

Ted Palma  
USEPA  
OAQPS/HEID/ATAG  
MD C539-02  
RTP, NC 27711

---

**From:** Steve Fudge <[sfudge@scainc.com](mailto:sfudge@scainc.com)>  
**Sent:** Tuesday, October 2, 2018 9:20 AM  
**To:** Palma, Ted  
**Cc:** Smith, Darcie; Morris, Mark  
**Subject:** RE: Proposed data dissemination plan - draft

## Ex. 5 Deliberative Process (DP)

Steve

---

**From:** Palma, Ted <Palma.Ted@epa.gov>  
**Sent:** Tuesday, October 2, 2018 8:01 AM  
**To:** Steve Fudge <sfudge@scainc.com>  
**Cc:** Smith, Darcie <Smith.Darcie@epa.gov>; Morris, Mark <Morris.Mark@epa.gov>  
**Subject:** Fw: Proposed data dissemination plan - draft

Steve

## Ex. 5 Deliberative Process (DP)

Ted Palma  
USEPA  
OAQPS/HEID/ATAG  
MD C539-02  
RTP, NC 27711

---

**From:** Strum, Madeleine  
**Sent:** Monday, October 1, 2018 7:11 PM  
**To:** Smith, Darcie; Palma, Ted  
**Cc:** Morris, Mark; Woody, Matthew; Eyth, Alison; Phillips, Sharon; Thurman, James  
**Subject:** Proposed data dissemination plan - draft

Hi

## Ex. 5 Deliberative Process (DP)

Let me know what you think and how best to address the questions.

Madeleine Strum|U.S. Environmental Protection Agency|109 TW Alexander Drive, RTP, NC 27711  
Office of Air Quality Planning and Standards|Air Quality Assessment Division|Emission Inventory and Analysis Group|919 541 2383

This email may contain privileged and confidential information intended only for the use of the specific entity named herein.

## Mahgoub, Gaida


---

**From:** Smith, Darcie  
**Sent:** Wednesday, October 3, 2018 10:29 AM  
**To:** Fry, Jessica  
**Subject:** RE: NATA Question

Hi Jessie –

I think what Alice was talking about is that soon we hope to be able to share block level data. As I understand it, that isn't something we normally do, but given the interest this time around, we're putting together an approach to be sure we consistently deliver the information. So, for now, the best I can do is say stay tuned...

Thanks for your question and please keep asking!  
Darcie

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Fry, Jessica  
**Sent:** Wednesday, October 03, 2018 9:49 AM  
**To:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Subject:** NATA Question

Hi Darcie,

I know I had asked you previously for the facility MRI data from NATA, but you said you were unable to provide that. Alice (Chow) and I were talking the other day and she mentioned that we would be able to get the block level risk around facilities? Is that correct, or something you could provide?

Thanks,  
Jessie

~~~~~  
Jessica Fry Chamberlin  
Office of Air Monitoring & Analysis (3AP40)  
Air Protection Division  
USEPA Region 3  
1650 Arch Street  
Philadelphia, PA 19103


Phone: (215) 814-2122  
Fax: (215) 814-2114  
Email: [fry.jessica@epa.gov](mailto:fry.jessica@epa.gov)  
~~~~~

## Mahgoub, Gaida

---

**From:** Smith, Darcie  
**Sent:** Thursday, October 4, 2018 8:00 AM  
**To:** Hollingsworth, Terri  
**Subject:** RE: Web Comment: NATA

Yes, will do. Thanks.

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Hollingsworth, Terri  
**Sent:** Thursday, October 04, 2018 7:30 AM  
**To:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Subject:** Fw: Web Comment: NATA

Hi Darcie,

As the NATA coordinator, would you please reply to Brendan's comment received via the NATA web portal?

thanks!

Terri

---

**From:** [drupal\\_admin@epa.gov](mailto:drupal_admin@epa.gov) <[drupal\\_admin@epa.gov](mailto:drupal_admin@epa.gov)> on behalf of Brendan Mascarenhas via EPA <[no-reply@epa.gov](mailto:no-reply@epa.gov)>  
**Sent:** Wednesday, October 3, 2018 3:55 PM  
**To:** Hollingsworth, Terri  
**Subject:** Web Comment: NATA

Submitted on 10/03/2018 3:54PM  
Submitted values are:

Name: Brendan Mascarenhas  
Email Address: [brendan\\_mascarenhas@americanchemistry.com](mailto:brendan_mascarenhas@americanchemistry.com)  
Comments:

Hello,

I have a couple quick questions on the NATA and would greatly appreciate the opportunity to discuss them with EPA. My questions have to do with EPA's future plans respective to the NATA and potential corrections. Any message back would be a big help--thanks a lot!

Regards,  
Brendan

**Mahgoub, Gaida**

---


**From:** Smith, Darcie  
**Sent:** Wednesday, October 3, 2018 11:30 AM  
**To:** Strum, Madeleine;Palma, Ted  
**Cc:** Morris, Mark;Woody, Matthew;Eyth, Alison;Phillips, Sharon;Thurman, James  
**Subject:** RE: Proposed data dissemination plan - draft

Hey Madeleine –

## Ex. 5 Deliberative Process (DP)

Anyway, those are my thoughts so far. I'll try to look at it again later today.

Thanks,  
Darcie

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Strum, Madeleine  
**Sent:** Monday, October 01, 2018 7:11 PM  
**To:** Smith, Darcie <Smith.Darcie@epa.gov>; Palma, Ted <Palma.Ted@epa.gov>  
**Cc:** Morris, Mark <Morris.Mark@epa.gov>; Woody, Matthew <Woody.Matthew@epa.gov>; Eyth, Alison <Eyth.Alison@epa.gov>; Phillips, Sharon <Phillips.Sharon@epa.gov>; Thurman, James <Thurman.James@epa.gov>  
**Subject:** Proposed data dissemination plan - draft

Hi  
See attached draft. I think with regards to emission inputs, there are no questions – we will continue to give these out.  
With regards to outputs, there are some questions – last column.

Let me know what you think and how best to address the questions.





## Mahgoub, Gaida

---

**From:** Smith, Darcie  
**Sent:** Thursday, October 4, 2018 4:34 PM  
**To:** Kelly Rimer; Davis, Alison; Cortelyou-Lee, Jan  
**Subject:** FW: NATA and ATSDR letter. V2. DRAFTKR.docx  
**Attachments:** NATA and ATSDR letter. V2. DRAFTKR\_dps.docx

Here's my revisions.

I'm going to be away from my desk for the next 30ish minutes, but then I'll be back if you need me.

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
 919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Rimer, Kelly  
**Sent:** Thursday, October 04, 2018 4:02 PM  
**To:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Subject:** NATA and ATSDR letter. V2. DRAFTKR.docx


Any chance you could take a quick look at this?

**Mahgoub, Gaida**

---

**From:** Smith, Darcie  
**Sent:** Thursday, October 4, 2018 9:46 AM  
**To:** Morris, Mark;Woody, Matthew  
**Subject:** RE: Draft modeling plan

Thanks! I've started on some larger context, background text, so I'll pull the two together and share.

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Morris, Mark  
**Sent:** Thursday, October 04, 2018 9:25 AM  
**To:** Smith, Darcie <Smith.Darcie@epa.gov>; Woody, Matthew <Woody.Matthew@epa.gov>  
**Subject:** Draft modeling plan

Here is a draft. This may not be worded for the general public, but I think all the pieces are there. Ex. 5 Deliberative Process (DP)

# Ex. 5 Deliberative Process (DP)

Mark Morris  
USEPA  
Mailcode C539-02  
109 TW Alexander Drive  
RTP, NC 27711  
(919) 541-5416  
[morris.mark@epa.gov](mailto:morris.mark@epa.gov)

## Mahgoub, Gaida

---

**From:** Smith, Darcie  
**Sent:** Thursday, October 4, 2018 8:07 AM  
**To:** Weinstock, Lewis  
**Subject:** RE: Weinstock, Lewis shared "Sampling Plan - EtO - Sterigenics Willowbrook - Draft" with you.


Thanks. I've been tasked with writing a modeling plan, so I'll model (ha!) it after yours.

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
[smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Weinstock, Lewis  
**Sent:** Wednesday, October 03, 2018 1:02 PM  
**To:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Subject:** Weinstock, Lewis shared "Sampling Plan - EtO - Sterigenics Willowbrook - Draft" with you.

Here's the document that Weinstock, Lewis shared with you.

 This link only works for the direct recipients of this message.



Sampling Plan - EtO - Sterigenics Willowbrook - Draft

Open



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Microsoft Corporation, One Microsoft Way, Redmond, WA 98052

## Mahgoub, Gaida

---

**From:** Smith, Darcie  
**Sent:** Friday, October 5, 2018 3:57 PM  
**To:** Kelly Rimer  
**Subject:** FW: Proposed data dissemination plan - draft  
**Attachments:** data\_dissemination\_proposed2.docx

In case this comes up while I'm out, here's the current plan. I've asked some questions and I think there is still more work needed before we start releasing anything. As a context reminder,

Ex. 5 Deliberative Process (DP)

### Ex. 5 Deliberative Process (DP)

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
smith.darcie@epa.gov

---

**From:** Strum, Madeleine  
**Sent:** Thursday, October 04, 2018 7:25 PM  
**To:** Smith, Darcie <Smith.Darcie@epa.gov>; Palma, Ted <Palma.Ted@epa.gov>  
**Cc:** Morris, Mark <Morris.Mark@epa.gov>; Woody, Matthew <Woody.Matthew@epa.gov>; Eyth, Alison <Eyth.Alison@epa.gov>; Phillips, Sharon <Phillips.Sharon@epa.gov>; Thurman, James <Thurman.James@epa.gov>  
**Subject:** RE: Proposed data dissemination plan - draft

Thanks for the comments. In the spirit of moving this forward in light of other higher priority goings-on, I have made modifications by adding a section on what is already available and, added a place for Ted/Sharon/James to input / comment in the updated version to follow up on some of your questions.

In addition:

## Ex. 5 Deliberative Process (DP)

Madeleine

Madeleine Strum | U.S. Environmental Protection Agency | 109 TW Alexander Drive, RTP, NC 27711  
Office of Air Quality Planning and Standards | Air Quality Assessment Division | Emission Inventory and Analysis Group | 919 541 2383

---


**From:** Smith, Darcie  
**Sent:** Wednesday, October 3, 2018 11:30 AM  
**To:** Strum, Madeleine <[Strum.Madeleine@epa.gov](mailto:Strum.Madeleine@epa.gov)>; Palma, Ted <[Palma.Ted@epa.gov](mailto:Palma.Ted@epa.gov)>  
**Cc:** Morris, Mark <[Morris.Mark@epa.gov](mailto:Morris.Mark@epa.gov)>; Woody, Matthew <[Woody.Matthew@epa.gov](mailto:Woody.Matthew@epa.gov)>; Eyth, Alison <[Eyth.Alison@epa.gov](mailto:Eyth.Alison@epa.gov)>; Phillips, Sharon <[Phillips.Sharon@epa.gov](mailto:Phillips.Sharon@epa.gov)>; Thurman, James <[Thurman.James@epa.gov](mailto:Thurman.James@epa.gov)>  
**Subject:** RE: Proposed data dissemination plan - draft

Hey Madeleine –

# Ex. 5 Deliberative Process (DP)

Anyway, those are my thoughts so far. I'll try to look at it again later today.

Thanks,  
Darcie

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Strum, Madeleine  
**Sent:** Monday, October 01, 2018 7:11 PM  
**To:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>; Palma, Ted <[Palma.Ted@epa.gov](mailto:Palma.Ted@epa.gov)>  
**Cc:** Morris, Mark <[Morris.Mark@epa.gov](mailto:Morris.Mark@epa.gov)>; Woody, Matthew <[Woody.Matthew@epa.gov](mailto:Woody.Matthew@epa.gov)>; Eyth, Alison <[Eyth.Alison@epa.gov](mailto:Eyth.Alison@epa.gov)>; Phillips, Sharon <[Phillips.Sharon@epa.gov](mailto:Phillips.Sharon@epa.gov)>; Thurman, James <[Thurman.James@epa.gov](mailto:Thurman.James@epa.gov)>  
**Subject:** Proposed data dissemination plan - draft

Hi  
See attached draft. I think with regards to emission inputs, there are no questions – we will continue to give these out.  
With regards to outputs, there are some questions – last column.

Let me know what you think and how best to address the questions.


Madeleine Strum | U.S. Environmental Protection Agency | 109 TW Alexander Drive, RTP, NC 27711  
Office of Air Quality Planning and Standards | Air Quality Assessment Division | Emission Inventory and Analysis Group | 919 541 2383

## Mahgoub, Gaida

---

**From:** Smith, Darcie  
**Sent:** Friday, October 5, 2018 3:52 PM  
**To:** Caparoso, Jennifer;Witt, Jon;Strum, Madeleine;Shappley, Ned;Koerber, Mike;Kelly Rimer;Riha, Kristin;Weinstock, Lewis;Chen, Xi;Lessard, Patrick;Jones, Rhea;Davis, Alison;Bremer, Kristen  
**Cc:** Morris, Mark;Woody, Matthew  
**Subject:** Updated - RE: Regional activity list  
**Attachments:** Fac List Reg Activities Oct 5 2018 backup copy.xlsx

Here's an updated list of activities. Still on [SharePoint](#), but attached just in case...

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)


---

**From:** Smith, Darcie  
**Sent:** Tuesday, September 18, 2018 10:29 AM  
**To:** Caparoso, Jennifer <Caparoso.Jennifer@epa.gov>; Witt, Jon <Witt.Jon@epa.gov>; Strum, Madeleine <Strum.Madeleine@epa.gov>; Shappley, Ned <Shappley.Ned@epa.gov>; Koerber, Mike <Koerber.Mike@epa.gov>; Kelly Rimer <Rimer.Kelly@epa.gov>; Riha, Kristin <Riha.Kristin@epa.gov>; Truesdell, Raymond <truesdell.raymond@epa.gov>; Weinstock, Lewis <Weinstock.Lewis@epa.gov>; Chen, Xi <Chen.Xi@epa.gov>; Lessard, Patrick <Lessard.Patrick@epa.gov>; Jones, Rhea <Jones.Rhea@epa.gov>; Cortelyou-Lee, Jan <Cortelyou-Lee.Jan@epa.gov>  
**Subject:** Regional activity list

Hi everyone –

I put together the attached table as a way to help us keep track of all the different activities. It is also on [Sharepoint](#) and that's the version I'll keep updated.

Thanks,  
Darcie


Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

## Mahgoub, Gaida

---

**From:** Smith, Darcie  
**Sent:** Monday, October 15, 2018 1:01 PM  
**To:** Witt, Jon  
**Subject:** RE: NATA V2 ?

Fyi - They don't have access to that file. I did send them one that was very similar and had a long word doc explaining it. Both should be in that same SP folder as the master ETOX file if you're interested. Likely dated feb or march of 2018.

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Witt, Jon  
**Sent:** Monday, October 15, 2018 12:48 PM  
**To:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Subject:** RE: NATA V2 ?

Susan Lancey from Region 1 had a question on the criteria that was used, but I just wanted to double-check with you first to be sure.

---


**From:** Smith, Darcie  
**Sent:** Monday, October 15, 2018 12:46 PM  
**To:** Witt, Jon <[Witt.Jon@epa.gov](mailto:Witt.Jon@epa.gov)>  
**Subject:** RE: NATA V2 ?

Hi Jonathan –

# Ex. 5 Deliberative Process (DP)

Why do you ask?

Darcie

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Witt, Jon  
**Sent:** Tuesday, October 09, 2018 10:14 AM  
**To:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Subject:** NATA V2 ?

Hi Darcie,

What was the criteria for including facilities on the V2 "MASTER ETOX" spreadsheet? Was it those facilities at a 100 in a million or higher block risk?

Thanks,  
Jonathan

---

**Jonathan W. Witt, EI**  
Environmental Engineer  
Office of Air Quality Planning and Standards  
EPA|OAR|OAQPS|SPPD|FIG  
109 T.W. Alexander Dr. | Mail Drop: E143-05 | Durham, NC 27703  
+1.919.541.5645 (work) | +1.919.541.7885 (fax)

## Mahgoub, Gaida


---

**From:** Smith, Darcie  
**Sent:** Monday, October 15, 2018 4:32 PM  
**To:** Jones, Rhea;Rimer, Kelly  
**Cc:** Sasser, Erika  
**Subject:** RE: Ethylene Oxide Update for Bill Wehrum for 10/18/18 visit

Hi Rhea –

I can do this, I just need a little more info first. What is the purpose, who's on point for the briefing, how long should it be, and who should be invited? Sorry for all the questions – I've been out the last week so I'm not up to date on where things stand. Maybe we can talk about this tomorrow at or after the 8:30?

Thanks,  
Darcie

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Jones, Rhea  
**Sent:** Monday, October 15, 2018 3:55 PM  
**To:** Rimer, Kelly <Rimer.Kelly@epa.gov>; Smith, Darcie <Smith.Darcie@epa.gov>  
**Cc:** Sasser, Erika <Sasser.Erika@epa.gov>  
**Subject:** Ethylene Oxide Update for Bill Wehrum for 10/18/18 visit

Hi Kelly and Darcie,

Added to the agenda for Bill Wehrum's visit to RTP on Thursday is an EtO update. It's currently on the itinerary for 3:30-4:15. Patrick is asking for a meeting request for this purpose, and once he receives it he will add it to the calendar. Darcie, could you help by preparing the meeting request? Please advise if you think someone else should be on point for this.

Thanks!



September 20, 2018

Information Quality Guidelines Staff  
Mail Code 2811R  
United States Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460

Re: Request for Correction under the Information Quality Act: 2014 National Air Toxics Assessment (NATA)

Dear Sir or Madam:

The Ethylene Oxide Panel of the American Chemistry Council (ACC), hereby submits this Request for Correction under the Information Quality Act (IQA) of 2000, Section 515 of the 2001 Treasury and General Government Appropriations Act, Pub. L. No. 106-554, the Office of Management and Budget (OMB) Guidelines for Ensuring and Maximizing the Quality, Utility, and Integrity of Information Disseminated by Federal Agencies,<sup>1</sup> and the Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency (EPA).<sup>2</sup> ACC represents producers and users of ethylene oxide (EO).

ACC seeks the correction of EO information disseminated in the 2014 update to the National Air Toxics Assessment (NATA), released on August 22, 2018.<sup>3</sup> The 2014 NATA relies upon the "Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75-21-8) In Support of Summary Information on the Integrated Risk Information System (IRIS)"<sup>4</sup> to determine the risk value for EO. As detailed below, the 2014 NATA does not meet the IQA's data quality requirements because the EO IRIS Assessment is not the best available science. Therefore, the 2014 NATA risk estimates for EO should be withdrawn and corrected to reflect scientifically-supportable risk values. Moreover, EPA should not use the EO IRIS Assessment's inhalation unit risk estimate (URE) of  $5 \times 10^{-3}$  per  $\mu\text{g}/\text{m}^3$ , which corresponds to a one-in-a-million increased cancer risk concentration of 0.1 parts per trillion (ppt), to calculate EO risk in

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<sup>1</sup> 67 Fed. Reg. 8452 (Feb. 22, 2002) (OMB Guidelines).

<sup>2</sup> Available at <https://www.epa.gov/sites/production/files/2017-03/documents/epa-info-quality-guidelines.pdf> (EPA Guidelines).

<sup>3</sup> Available at <https://www.epa.gov/national-air-toxics-assessment/2014-nata-assessment-results> (2014 NATA).

<sup>4</sup> EPA/635/R-16/350Fa (December 2016) (EO IRIS Assessment).



its ongoing Clean Air Act (CAA) Section 112 risk and technology review (RTR) rulemakings and other regulatory actions.<sup>5</sup>

As producers and users of EO, ACC members are directly impacted by the errors in the 2014 NATA. The risk estimates based on the EO IRIS value have significant regulatory implications for ACC member companies who produce commercial products of value to consumers using EO. Correcting these deficiencies will result in more accurate estimates of potential risk that will lead to improved regulatory outcomes, the dissemination of more accurate information to the public, and overall reduced misconception.

This Request for Correction is organized into four sections. The Executive Summary provides a high level overview of the key reasons why the 2014 NATA does not meet the objectivity, accuracy, integrity and utility requirements of the IQA and the OMB and EPA Guidelines due to its reliance on the EO IRIS Assessment. The second section provides background information on the 2014 NATA and the EO IRIS Assessment. The third section highlights the information in the EO IRIS Assessment that is not scientifically supportable. In the last section, each of the key deficiencies in the EO IRIS Assessment is discussed in detail with supporting scientific evidence.

## I. Executive Summary

In the 2014 NATA, EPA relies on updated benchmarks for several substances, including EO. For EO, EPA updated its cancer risk calculations to reflect the URE in the EO IRIS Assessment. The use of the URE value, however, results in inaccurate and misleading conclusions about EO risk.

The EO IRIS Assessment is based on a supralinear spline slope for lymphoid and breast cancer exposure-response analyses from an epidemiology study conducted by the National Institute for Occupational Safety and Health (NIOSH). **This supralinear risk assessment model predicts high risk at low exposures, lower risk at higher exposures, and estimates an unrealistically low concentration of 0.1 ppt.** This  $10^{-6}$  risk specific concentration (RSC) is the lower bound lifetime chronic exposure level of EO that corresponds to an increased cancer risk of one-in-a-million. **Both the supralinear slope and the RSC are implausible based on the epidemiological evidence and biological mode of action.**

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<sup>5</sup> In a recently proposed RTR rule, EPA solicits comment on whether it should ban the use of EO for one of the source categories. *NESHAP; Surface Coating of Large Appliances; Printing, Coating, and Dyeing of Fabrics and Other Textiles; and Surface Coating of Metal Furniture Residual Risk and Technology Reviews*, 83 Fed. Reg. 46262, 46294 (Sept. 12, 2018).

In addition, these implausible levels lack utility for regulatory purposes. **The RSC in the EO IRIS Assessment is 19,000 times lower than the air-concentration equivalent yielding normal, endogenous levels of EO in the human body. Likewise, the RSC is orders of magnitude lower than ambient levels of EO.** Thus, if the EO IRIS Assessment is to be believed, normal human metabolism and/or breathing ambient air is sufficient to cause cancer. The EO IRIS Assessment does not provide a meaningful basis for assessing and managing risk for EO.

As outlined below, the EO IRIS Assessment is substantially flawed and can be corrected by using the approach published by Valdez-Flores et al. (2010),<sup>6</sup> which models potential mortality excesses for lymphohematopoietic tissue (LH) cancers from the two strongest epidemiological studies (NIOSH and Union Carbide Corporation (UCC)) using a log-linear Cox proportional hazard model. **Valdez-Flores et al. (2010) estimated ranges for the maximum likelihood estimate (MLE) and the 95% lower confidence limit of the environmental concentration corresponding to an extra risk of one in a million [LEC (1/million)] of, respectively, 1.5-9.2 parts per billion (ppb) and 0.5-1.2 ppb.** The major reason for the large difference between these values and the EO IRIS Assessment estimates is that the IRIS Program uses a supralinear spline model and Valdez-Flores et al. (2010) uses the log-linear Cox model.

EPA's cancer risk assessment guidelines caution that "a steep slope [i.e., supralinear] also indicates that errors in an exposure assessment can lead to large errors in estimating risk."<sup>7</sup> This is relevant to the EO IRIS Assessment because the NIOSH exposure model has a much higher level of uncertainty between the late 1930s and 1978 when there was inadequate (1976-78) or no exposure data (<1976) to independently validate the model. Furthermore, the NIOSH exposure model was modified when estimating exposures prior to 1978 by fixing the effect of a key variable (calendar year) in the model.

Specifically, Hornung et al. (1994) determined that Calendar Year is a major predictor of exposure in the model after 1978, but they did not allow this variable to impact exposures in the model prior to 1978.<sup>8</sup> Hornung et al. (1994) surmised that Calendar Year acts as a surrogate for improvement in work practices. **Thus, the arbitrary decision to alter the model prior to 1978 essentially assumes there were no evolving work practices in contract sterilizer facilities**

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<sup>6</sup> Valdez-Flores C, Sielken RL Jr, Teta MJ. 2010. Quantitative cancer risk assessment based on NIOSH and UCC epidemiological data for workers exposed to ethylene oxide. Regul Toxicol Pharmacol, 56(3): 312-20.

<sup>7</sup> EPA, Guidelines for Carcinogen Risk Assessment (March 2005), at 3-19. Available at <https://www.epa.gov/risk/guidelines-carcinogen-risk-assessment>

<sup>8</sup> Hornung RW, Greife AL, Stayner LT, Steenland NK, Herrick RF, Elliott LJ, Ringenburg VL, Morawetz J. 1994. Statistical model for prediction of retrospective exposure to ethylene oxide in an occupational mortality study. Am J Ind Med, 25(6): 825-36.

**between 1938 and 1977 that influence exposure to workers.** The EO IRIS Assessment did not critically evaluate the assumptions and uncertainties of the NIOSH exposure model.

Moreover, the EO IRIS Assessment makes an unsubstantiated and counter-intuitive claim that the EO sterilization process was historically constant and stable prior to 1978. Yet, even the authors of the NIOSH study predict higher exposures before installation of engineering controls (“e.g., increased ventilation and better door seals”) in 1978, when OSHA standards were higher.<sup>9</sup> **Below, we provide information on evolving regulatory standards, residue levels of EO, equipment, engineering and processing practices that indicate that the NIOSH exposure model incorrectly predicted that exposures would decrease in earlier years compared to the 1970s for the most exposed jobs (e.g. sterilizer operator). In general, *underestimating exposures will overestimate risk*, and the EPA cancer risk assessment guidelines caution that use of a supralinear model will further exacerbate the impact of these exposure errors.**

**The rationale for selecting the supralinear spline model is based on incorrect statistical procedures and visual misrepresentation of the data.** The EO IRIS Assessment incorrectly calculates the statistical significance (e.g., p- and AIC values) of the supralinear spline dose-response model because it fails to account for the statistical impact of the trial-and-error exploration of different arbitrary values used in the EO IRIS Assessment’s dose-response model, such as the exposure level where the slope changes in the model from a very steep slope to a shallow slope (i.e. the “knot”).<sup>10</sup> In addition, the figures used to compare visual fits use categorical data rather than the individual cases that were modeled. Once the individual cases are used, the log-linear Cox model fits the data just as well as the more complex and ill-advised supralinear spline model. The log-linear Cox model best meets the objective of selecting the more parsimonious model with fewer assumptions and variables.

Biologically, selection of the log-linear Cox model is more consistent with the mode of action for EO. This is supported by the EO IRIS Assessment, which concludes it is “highly plausible that the dose-response relationship over the endogenous range is sublinear ... that is, that the slope of the dose-response relationship for risk per adduct would increase as the level of endogenous adducts increases.”<sup>11</sup>

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<sup>9</sup> Steenland K, Stayner L, Greife A, Halperin W, Hayes R, Hornung R, Nowlin S. 1991. Mortality among workers exposed to ethylene oxide. *N Engl J Med*, 324(20): 1402-07.

<sup>10</sup> See, e.g., Li W, He C, Freudenberg J. 2011. A mathematical framework for examining whether a minimum number of chiasmata is required per metacentric chromosome or chromosome arm in human. *Genomics*, 97(3): 186-92.

<sup>11</sup> EO IRIS Assessment, at 4-95.

Both the UCC and NIOSH studies should be included in the dose-response modeling so that the risk estimates are based on the best available human data. Although the NIOSH study cohort is much larger, both studies have comparable power for males when considering the number of events of interest, i.e., lymphohematopoietic tissue cancers. The EO IRIS Assessment excludes the UCC cohort based primarily on a comparison of the exposure assessments for both studies. The EO IRIS Assessment dismisses the UCC exposure estimates as “crude,” “largely-uninformative,” “much less extensive,” and “greater likelihood for exposure misclassification,” as compared with the NIOSH study, which is described as “well-validated” and “high-quality.” These descriptions lack objectivity and obscure the fact that the majority of the UCC cohort exposure estimates are based on contemporary data from different plants with identical or comparable processes. **Although the NIOSH exposure model was validated with data after 1978, there were no contemporary data between the late 1930s and mid-1970s to validate the final model. Thus, the UCC exposure assessment uncertainties are no greater than the NIOSH study uncertainties and, therefore, are not a valid reason to exclude the UCC cohort.**

The EPA Science Advisory Board’s (SAB) peer review of the draft EO IRIS Assessment did not remedy the shortcomings of the final EO IRIS Assessment. The presumption of objectivity that sometimes attaches to documents that have been peer reviewed does not apply in this case because authors of the NIOSH study influenced the analysis of the data as well as the responses to the SAB’s comments. This influence compromised the objectivity and independent analysis of the NIOSH study, and especially the NIOSH exposure model, in the draft and final EO IRIS Assessments.

## **II. The 2014 NATA and the EO IRIS Assessment**

The 2014 NATA uses emissions information to help state, local, and tribal air agencies identify which pollutants, emission sources, and places may warrant a better understanding for any possible risks to public health from air toxics. EPA further uses NATA results to improve data in emission inventories; identify where to expand air toxics monitoring; help target risk reduction activities; identify pollutants and source types of greatest concern; help decide what other data to collect; better understand risks from air toxics; and work with communities to design their own assessment.

The 2014 NATA results list EO emissions information across a range of categories, including location, cancer risks, hazard quotients, source type (e.g., stationary sources, mobile, airports, etc.). In building the NATA, EPA must select specific risk levels for certain air toxics that can lead to determinations of acceptable or unacceptable thresholds. Since air toxics have no universal, predefined risk levels that clearly represent acceptable or unacceptable thresholds,

EPA makes case-specific determinations and general presumptions that apply to certain regulatory programs that further inform the interpretation of risk in the NATA. These benchmarks are drawn from a range of sources and updated. EPA notes that several substances' benchmarks were updated since the 2011 NATA, including EO. Specifically, EPA states that its risk value for EO was updated in 2016—the newly finalized IRIS value. As such, EPA updated its cancer risk calculations to reflect this new updated benchmark value. Due to the use of the EO IRIS value, more areas show elevated risks driven by EO in the 2014 NATA than in the 2011 NATA, even if emissions levels have stayed the same, or even decreased, in these areas.

The alleged elevated cancer risk driven by EO in the 2014 NATA has already caused alarm in some communities around facilities with EO emissions. This, in turn, has created media attention, and coverage of the issue has created further confusion and concern in the surrounding community. All of this could have been avoided had EPA relied on the best available science in calculating the unit risk estimate for cancer.

As discussed in detail below, the use of the updated EO IRIS value in the 2014 NATA and its Technical Support Document is extremely problematic given the EO IRIS Assessment's numerous shortcomings. A simple comparison of the results of the EO IRIS Assessment to the "real world," however, demonstrates its lack of credibility. Specifically, the RSC is 19,000 times *lower* than the normal, endogenous levels of EO in the human body. Likewise, the RSC is orders of magnitude *lower* than ambient levels of EO. Thus, if the EO IRIS Assessment is to be believed, normal human metabolism and/or breathing ambient air, without more, is sufficient to cause cancer. It strains scientific credibility to conclude that the EO IRIS Assessment presents a legitimate basis for determining risk for EO.

### **III. Request for Correction**

The 2014 NATA relies upon the EO IRIS Assessment's inhalation URE of  $5 \times 10^{-3}$  per  $\mu\text{g}/\text{m}^3$  to calculate EO risk. This URE implies a corresponding RSC of 0.1 ppt. The use of these values, however, results in inaccurate and misleading conclusions about EO risk because they are not supported by the scientific data. The RSC is also unrealistic, given that it is orders of magnitude lower than levels of EO in ambient air and levels that are consistent with normal, endogenous levels of EO present in human bodies.

A more reasonable and scientifically supportable approach to an exposure response analysis yields ranges for the MLE (1.5-9.2 ppb) and LEC (0.5-1.2 ppb) that are more than three orders of magnitude greater than the RSC.<sup>12</sup> Moreover, the ranges of MLE and LEC values are

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<sup>12</sup> Valdez-Flores et al. (2010).

conservative because (a) extra risk was calculated despite no statistically significant slope in the exposure-response analyses; (b) the NIOSH data was included without adjustment for likelihood of underestimation of exposures; and (c) the limited evidence of cancer risk based on the entire body of epidemiologic evidence (see Appendix 2). The 2014 NATA risk estimates for EO should be withdrawn and corrected to reflect these risk values. Moreover, EPA should not use the EO IRIS Assessment's RSC of 0.1 ppt or URE of  $5 \times 10^{-3}$  per  $\mu\text{g}/\text{m}^3$  to calculate EO risk in its ongoing CAA Section 112 risk and technology review or other rulemakings.

**A. The 2014 NATA Does Not Meet the Objectivity, Integrity, and Utility Requirements of the IQA and the OMB and EPA Guidelines.**

Congress enacted the Information Quality Act (IQA) to “ensur[e] and maximiz[e] the quality, objectivity, utility and integrity of information (including statistical information) disseminated by Federal agencies” such as EPA.<sup>13</sup> The IQA required OMB to issue government-wide guidance, which each federal agency was to follow in its issuance of its own guidelines. The purpose of the EPA Guidelines is to apply the OMB Guidelines to the Agency’s particular circumstances, and to “establish administrative mechanisms allowing affected persons to seek and obtain correction of information ... disseminated by the agency that does not comply with the [OMB] guidelines....”<sup>14</sup> The 2014 NATA, therefore, must meet the OMB Guidelines as well as the EPA Guidelines.

OMB Guidelines include clear definitions to guide agency practices in adhering to the IQA. These include:

- “‘Information’ means any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms.”<sup>15</sup>
- “‘Influential,’ when used in the phrase ‘influential scientific, financial, or statistical information,’ means that the agency can reasonably determine that dissemination of the information will have a clear and substantial impact on important public policies or important private sector decisions.”<sup>16</sup>

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<sup>13</sup> See Pub. L. No. 106-554. The IQA was developed as a supplement to the Paperwork Reduction Act, 44 U.S.C. §3501 et seq., which requires OMB, among other things, to “develop and oversee the implementation of policies, principles, standards, and guidelines to ...apply to Federal agency dissemination of public information.”

<sup>14</sup> Pub. L. No. 106-554.

<sup>15</sup> OMB Guidelines, at 8460.

<sup>16</sup> *Id.*

- “‘Objectivity’ involves two distinct elements, presentation and substance. ‘Objectivity’ includes whether disseminated information is being presented in an accurate, clear, complete, and unbiased manner.... In addition ‘Objectivity’ involves a focus on ensuring accurate, reliable, and unbiased information. In a scientific, financial, or statistical context, the original and supporting data shall be generated, and the analytic results shall be developed, using sound statistical and research methods.”<sup>17</sup>
- “‘Utility’ refers to the usefulness of the information to its intended users, including the public. In assessing the usefulness of information that the agency disseminates to the public, the agency needs to consider the uses of the information not only from the perspective of the agency but also from the perspective of the public. As a result, when transparency of information is relevant for assessing the information’s usefulness from the public’s perspective, the agency must take care to ensure that transparency has been addressed in its review of the information.”<sup>18</sup>

The 2014 NATA is influential scientific risk assessment information and must adhere to a rigorous standard of quality.<sup>19</sup> The 2014 NATA is “influential” scientific risk assessment information as set forth in the EPA Guidelines because it “will have or does have a clear and substantial impact (i.e., potential change or effect) on important public policies or private sector decisions” and involves “controversial scientific ... issues.”<sup>20</sup> Results from the NATA are used by government agencies, non-governmental organizations, and air quality experts to gauge which hazardous air pollutants (HAP) and emission sources may raise health risks in certain places. These places are then given more attention and EPA uses the NATA to, among other things, target ways to achieve risk reduction.

The NATA can also lead to the development of local community-supported plans to reduce emissions as presented in each NATA version’s results. Additionally, the National Research Council (NRC) has recognized the NATA as one of the largest EPA efforts to “develop baseline cancer risk estimates and hazard index calculations using dose-response information and exposure estimates.”<sup>21</sup> In this context, NRC further acknowledges the importance of the NATA as a “tool for exploring control priorities” and its function “as a preliminary attempt to establish a

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<sup>17</sup> *Id.* at 8459.

<sup>18</sup> *Id.*

<sup>19</sup> Quality includes objectivity, utility, and integrity.

<sup>20</sup> See EPA Guidelines, at 19-20 (internal citations omitted); OMB Guidelines, at 8455.

<sup>21</sup> National Research Council, “Air Quality Management In the United States” (2004), at 247. Available at <https://www.nap.edu/read/10728/chapter/1>.



baseline for tracking progress in reducing HAP emissions.”<sup>22</sup> Therefore, the 2014 NATA, and its underlying data, must adhere to a rigorous standard of quality, including meeting the higher standard of reproducibility.

With regard to the analysis of risks to human health, safety and the environment maintained or disseminated by the agencies, the OMB and EPA Guidelines also require either adoption or adaption to “the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act Amendments of 1996 (42 U.S.C. 300g-1(b)(3)(A) & (B)).”<sup>23</sup> In ensuring the objectivity of influential scientific risk information (i.e., the substance of the information is accurate, reliable and unbiased), the EPA Guidelines have adapted these principles by requiring the use of the “best available science and supporting studies” and the collection of data using by “accepted methods or the best available methods” using “a ‘weight-of-evidence’ approach that considers all relevant information and its quality.”<sup>24</sup>

EPA has failed to apply a transparent and systematic weight-of-evidence approach in assessing the cancer risks of EO exposures in the 2014 NATA. Moreover, as detailed below, because the 2014 NATA relies upon the EO IRIS Assessment to determine the risk value for EO, the 2014 NATA is not based on the best available science.

## **B. The EO IRIS Assessment Does Not Meet Scientific Standards from Multiple Standpoints.**

The EO IRIS Assessment is not the best available science because it: (1) exclusively relies on a NIOSH study despite its flawed exposure assessment; and (2) applies a supra-linear spline model, which is implausible based on the epidemiological and biological evidence and deficient due to statistical miscalculations and visual misrepresentations.

1. The EO IRIS Assessment incorrectly describes the NIOSH exposure model as a “state-of-the-art” validated regression model to estimate historical exposures prior to 1978. In fact, this “state-of-the-art” validated model was tested with post-1978 data only and arbitrarily altered for years prior to 1978. Specifically, a variable considered to be a major predictor of exposure after 1978 was not allowed in the model to impact exposures prior to 1978. The

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<sup>22</sup> *Id.*

<sup>23</sup> See EPA Guidelines, at 22-23; OMB Guidelines, at 8460.

<sup>24</sup> See EPA Guidelines, at 21-22. “In this approach, a well-developed, peer-reviewed study would generally be accorded greater weight than information from a less well-developed study that had not been peer-reviewed, but both studies would be considered.” *Id.* at 26. The definition of best available science mirrors that articulated in *Chlorine Chemistry Council v. EPA*, 206 F.3d 1286 (D.C. Cir. 2000), referring to “the availability at the time an assessment is made.” See EPA Guidelines, at 23.



reliability, validation and likelihood of exposure misclassification prior to 1978 were not objectively evaluated.

2. The results of NIOSH's statistical model for exposures prior to 1978 were not provided in the 2014 Draft EO IRIS Assessment or in the cited NIOSH publications. In the appendices of the final EO IRIS Assessment, two new figures (Figures D-22 and D-33) present new information on estimated exposures by worker, but no explanation or critical evaluation was added. There is a lack of transparency in the EO IRIS Assessment of these influential data used to derive the EO cancer slope factor.

3. The EO IRIS Assessment repeatedly asserts that the NIOSH exposure estimates were well-validated using a state-of-the-art model, when in fact there was no validation of exposure estimates prior to 1978. These assertions regarding verification procedures are incorrect for the late 1930s to 1978.

4. In response to public and SAB comments questioning the lower than expected exposures in earlier years predicted by the statistical regression model, the IRIS Program states that the decrease is related to the sterilizer volume. In other words, the model predicts that smaller sterilizer volume results in lower exposures. This response essentially uses the output of the model to answer a question about whether the model assumptions are correct, instead of independently verifying the validity of these assumptions. This circular reasoning does not address the underlying concern of whether the model assumption that Sterilizer Volume has an inverted parabolic (that is, an upside-down U-shaped) relationship with predicted EO exposure is correct. It also does not address whether other factors that might result in increased exposure during early years were properly accounted for in the model.

5. The EO IRIS Assessment makes the unsubstantiated claim that "the sterilization processes used by the NIOSH cohort workers were fairly constant historically, unlike chemical production processes, which likely involved much higher and more variable exposure levels in the past."<sup>25</sup> In fact, there was an evolution in technology and practices associated with the sterilization processes between the late 1930s and early 1970s. Data and information from industrial sterilization operators and the literature refute this claim.

6. Comparisons of relative reliability made between the NIOSH and UCC studies are inaccurate. These comparisons were a key basis upon which the IRIS Program rejected the UCC Study as a source of epidemiology study data for cancer risk assessment. The EO IRIS Assessment does not acknowledge and appropriately consider limitations of the NIOSH

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<sup>25</sup> EO IRIS Assessment, at 4-4.

exposure assessment posed by low extrapolations of NIOSH cohort exposures to EO prior to the late 1970s without any corroborating data or any supporting engineering/process considerations derived from or directly relevant to that period of time.

7. The EO IRIS Assessment relies solely on the NIOSH study of sterilant workers and fails to incorporate the important findings from the UCC study of workers in EO producing and using operations. The IRIS Program considered and characterized three factors in its selection of the NIOSH study: cohort size, exposure data, and confounding. Based on these factors, the IRIS Program dismissed the UCC study as a basis for EO cancer risk estimation. In considering cohort size, the IRIS Program ignored the most important comparison—the number of lymphohematopoietic tissue cancers, not the total cohort size.

8. The use of the supralinear spline model for the lymphoid and breast cancers in the final EO IRIS Assessment is based on an invalid statistical analysis. Because the analysis did not correctly calculate degrees of freedom associated with that fitted model, it contains erroneous measures of absolute and relative goodness of fit of that model. When both the p-values and Akaike Information Criterion (AIC) values characterizing fit quality are corrected, the supralinear spline model does not fit the NIOSH lymphoid tumor data statistically significantly better than the log-linear Cox model.

9. The selection of the supralinear spline model for the lymphoid tumors is also based on misleading illustrations of “visual fits” that do not convey either the actual data that were fit or the relative goodness of fit to these data of log-linear and supralinear spline models. Only in a footnote does the IRIS Program indicate that the visual comparison misrepresents the log-linear model being compared. Consequently, and erroneously, the fit to the data appears far worse than the supralinear spline model. The data plotted in that figure also were summary data that misrepresent the true magnitude of the scatter of the data that were used for model fitting.

10. The selection of a spline model as the preferred model for EO cancer risk estimation assumes a supralinear increase in tumor response in the low-dose exposure region with a subsequent plateauing of response at higher exposures. The body of cancer epidemiologic studies, including the NIOSH studies, does not support such a pattern of risk. While certain NIOSH sub-analyses suggest increases in male lymphoid tumors and female breast cancers, the findings are limited to the highest cumulative exposure groups, not the lowest.

11. The use of a supralinear spline model for cancer risk estimation is inconsistent with the assumed mode-of-action of EO toxicity and tumorigenicity. Such a model predicts higher risk at low exposures compared to risks predicted at higher exposures, which is contradicted by the well-understood mode of action of EO in experimental animals and humans

as described in the EO IRIS Assessment. Thus, the EO IRIS Assessment relies on human cancer risk estimates based on spline-model dose-response extrapolations that are internally inconsistent with its own evaluation of the mode of action of EO. The mean air concentration equivalent to the endogenous concentration in non-smoking humans with no known EO exposures is 1.9 ppb (range 0.13-6.9 ppb; continuous), which is 19,000 times greater than the EO IRIS RSC of 0.1 ppt.<sup>26</sup> An alternative LEC (1/million) of 0.5-1.2 ppb is a more pragmatic, science-based approach for EO risk assessment.

12. The statistical, epidemiological and biological evidence does not support the selection of supralinear spline models to fit the NIOSH study data in the EO IRIS Assessment. A more scientifically sound conservative alternative is to use the Valdez-Flores et al. (2010) approach, which incorporates all the available data from the two strongest human studies (NIOSH and UCC). This approach has been adopted by the European Commission's Scientific Committee on Occupational Exposure Limits.<sup>27</sup>

#### **IV. Because the 2014 NATA Relies Upon the EO IRIS Assessment to Determine the Risk Value for EO, the 2014 NATA Is Not Based on the Best Available Science.**

- 1. The EO IRIS Assessment incorrectly describes the NIOSH exposure model as a “state-of-the-art” validated regression model to estimate historical exposures prior to 1978. In fact, this “state-of-the-art” validated model was tested with post-1978 data only and arbitrarily altered for years prior to 1978. Specifically, a variable considered to be a major predictor of exposure after 1978 was not allowed in the model to impact exposures prior to 1978. The reliability, validation and likelihood of exposure misclassification prior to 1978 were not objectively evaluated.**

The EO IRIS Assessment's evaluation of the cancer potency of EO is dependent on an analysis of commercial sterilization worker exposure conducted by NIOSH. The NIOSH EO data for the sterilization work cohort were nearly all collected between 1978 and 1986 at 20 different facilities, but included just seven mean values based on 23 exposure measurements for the period 1976-77.<sup>28</sup> Ultimately, of the 20 facilities, 16 facilities were eliminated from the

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<sup>26</sup> Kirman CR, Hays SM. 2017. Derivation of endogenous equivalent values to support risk assessment and risk management decisions for an endogenous carcinogen: Ethylene oxide. *Regul Toxicol Pharmacol*, 91: 165-72.

<sup>27</sup> See Recommendation from the Scientific Committee on Occupational Exposure Limits for ethylene oxide, SCOEL/SUM/160 (June 2012).

<sup>28</sup> Hornung et al. (1994).

exposure assessment for lack of personal sampling, documentation of sampling, or links of sampling to job categories.

Based on the available worker data, the workers included in the NIOSH study cohort were employed in the sterilization industry as early as the 1930s. Noting that “there were no measurement data prior to 1976,” Hornung et al. (1994) describe the statistical model<sup>29</sup> developed to estimate NIOSH EO-cohort worker exposures based on data collected after 1978. That model was applied to estimate worker exposures over a large timespan (1935-1975) during which not a single observed measurement was available to validate the application of that model extrapolation procedure.

Although the NIOSH statistical regression model estimated exposure measurements after 1977 with reasonable reliability, Hornung et al. (1994) highlighted that post-1978 regulatory standards and consequent progressively stringent operational EO-exposure controls accounted for the pronounced decreasing trend in measured NIOSH-cohort EO exposures that occurred after 1978. Prior to 1978, these EO standards and controls were largely or entirely absent. Thus, they were irrelevant to most of the 1935-1975 timespan, during which time the NIOSH statistical model was applied to estimate historical worker exposures without any empirical physical-modeling basis for direct validation.

The final statistical model selected to predict the natural logarithm (ln) of EO exposure included two nonlinearly modeled variables which were determined to be the two most EO-predictive variables identified: Calendar Year (“Year”) and Sterilizer Volume (“Cubic Feet”). These two variables were each modeled to have an inverted parabolic relationship to predicted ln(EO) levels, resulting in predicted peak EO exposures to occur during 1978 as a function of Year. Hornung et al. (1994) note that their final statistical model arbitrarily set the value of Year to be 1978 for all years prior to 1978, explaining that:

Since we felt that the decrease in ETO levels after 1978 (independent of engineering controls) was explained by improved work practices after ETO was identified as a potential carcinogen, we set each predicted ETO level prior to 1978 equal to the predicted level in 1978. Variation in exposure levels prior to 1978 were modeled as a function of the remaining terms in the model with the calendar year effect fixed at 1978. Therefore, there was no extrapolation by calendar year prior to 1978.

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<sup>29</sup> Steenland NK, Stayner LC, Griefe AL. 1987. Assessing the feasibility of retrospective cohort studies. *Am J Ind Med*, 12: 419-30; Greife AL, Hornung RW, Stayner LG, Steenland KN. 1988. Development of a model for use in estimating exposure to ethylene oxide in a retrospective cohort mortality study. *Scand J Work Environ Health*, 14(Suppl 1): 29-30.

Thus, the “validated” model was arbitrarily and selectively altered for years prior to 1978 by fixing the calendar year value to 1978. Nonetheless, for the same period prior to 1978, the model still predicts that lower EO sterilizer volumes were associated with lower occupational EO exposures—a prediction made without any independent, pre-1978 measurement-based or physical-modeling-based evidence supporting such an association during that period. The IRIS Program should have questioned the reliability and validation of the model prior to 1978, and objectively considered the likelihood of exposure misclassification during this period.

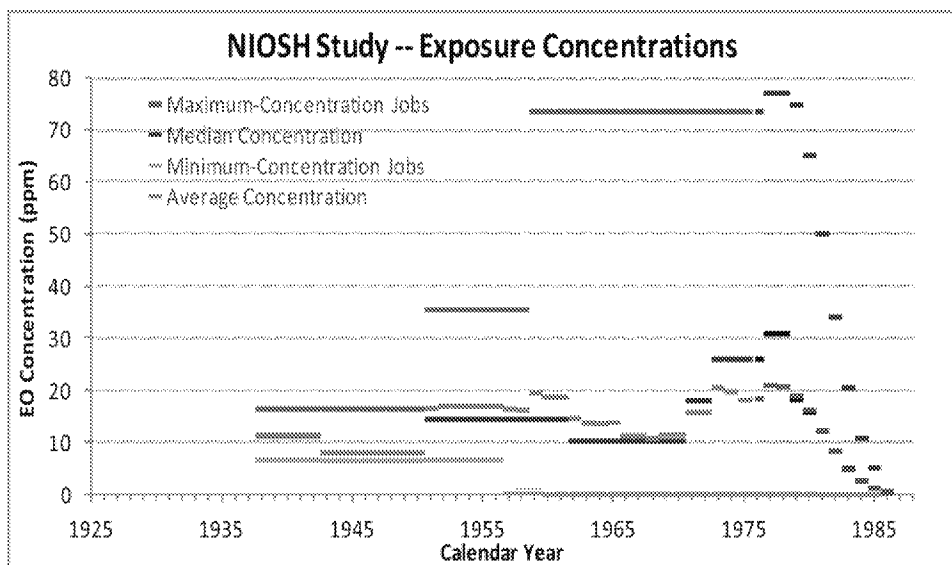
- 2. The results of NIOSH’s statistical model for exposures prior to 1978 were not provided in the 2014 Draft EO IRIS Assessment or in the cited NIOSH publications. In the appendices of the final EO IRIS Assessment, two new figures (Figures D-22 and D-33) present new information on estimated exposures by worker, but no explanation or critical evaluation was added. There is a lack of transparency in the EO IRIS Assessment of these influential data used to derive the EO cancer slope factor.**

A basic standard quality expectation for a peer-reviewed publication of a statistical model for exposure is that the results section should include summary of the output of the model; in other words, the estimated exposures resulting from the model. Neither the NIOSH exposure modeling publications nor the NIOSH epidemiology studies that rely on this model provide any descriptive summary of exposures estimated by the model prior to the late 1970s. The IRIS Program should have independently evaluated the exposure data, especially after ACC provided the summary of NIOSH exposures by job (reprinted below as Figure 1).

Figures D22 and D23 in the EO IRIS Assessment are graphs of estimated annual exposures for the entire cohort by worker, but not by job. However, there is no discussion or analysis of these graphs in either Appendix D or the main report. These figures are less informative in understanding how the NIOSH exposure model estimated exposure by job because these figures are based on each worker who could have different job assignments. Nevertheless, the 95<sup>th</sup> percentile of annual exposures of the NIOSH cases in Figure D-23 has a very similar pattern of exposures as the job with the maximum exposure in Figure 1 below.

As described below, neither Hornung et al. (1994) nor the IRIS Program offer any realistic explanation for the counterintuitive trend backward in time from the late 1970s that is predicted by the NIOSH statistical regression model, other than such a trend just happens to be what that statistical model predicts. Thus, there is a lack of transparency and independent critical evaluation of the exposure estimates of the NIOSH exposure model in the EO IRIS Assessment.

Moreover, the derivation of the NIOSH statistical regression model can no longer be reproduced, because the raw data on which it was based no longer exist.<sup>30</sup>

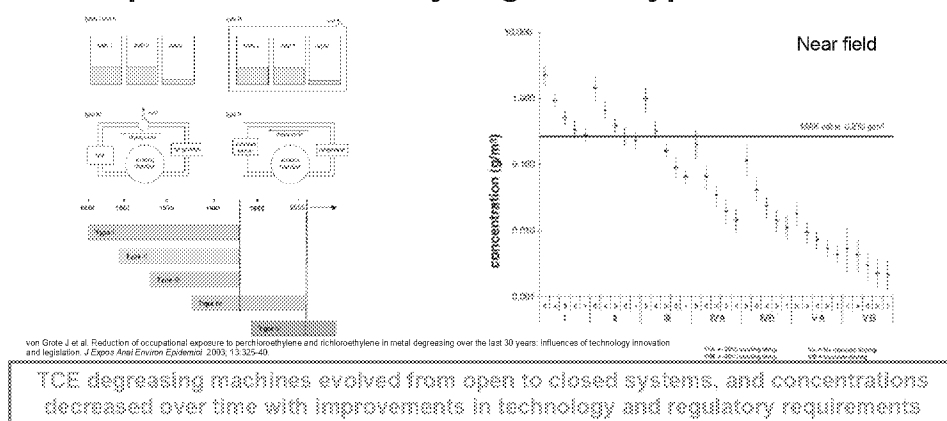


**Figure 1.** NIOSH statistical regression model predictions of 8-hour time-weighted average exposure to EO by job in each calendar year. This summary data for each job was provided by NIOSH and was used to estimate exposures for participants in the NIOSH cohort based on job code. This figure appeared on page 173 of Appendix M (“Comments on NIOSH Exposure Papers: Greife et al. (1988) and Hornung et al. (1994)”) of Comments on the Revised External Review Draft Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide, Docket ID No. EPA-HQ-ORD-2006-0756 submitted to EPA by ACC on October 11, 2013, but did not appear either in Hornung et al. (1994) or any of the draft EO IRIS Assessments reviewed by SAB.

<sup>30</sup> Appendix H (Summary of 2007 External Peer Review and Public Comments And Disposition) of the EO IRIS Assessment states, “[i]n response to the panel’s suggestion that the Hornung analysis represents an ‘invaluable opportunity’ for further analysis of the impact of possible errors in exposure estimation, the EPA investigated the possible use of the ‘errors in variables’ approach (page 27 of the panel report). Steenland visited the NIOSH offices in Cincinnati in order to review the data and assess whether it would support an errors-in-variables analysis. Unfortunately, the electronic data files used in the [NIOSH] exposure analysis were no longer available, so that analysis based on the errors-in-variables approach was not possible.” *Id.* at H-28. Thus, the raw data on which NIOSH relied to derive its statistical regression model used to extrapolate historical NIOSH-cohort exposures to EO prior to the late-1970s, when measures of workplace EO first began to be made, no longer exist—implying that there is no longer any way to validate the claim by Hornung et al. (1994) that their model was able to predict the 85% of the variation in log values of EO concentrations measured starting in the late-1970s. Even if that claim were true, it has no logical bearing on the ability of that model to generate accurate extrapolations of occupational exposure to EO back in time prior to the late 1970s when, as emphasized by Hornung et al. (1994), occupational conditions were quite different because none or virtually none of many sterilization technology changes and sterilization workplace practices, which only began to be adopted starting in the late 1970s to greatly reduce EO exposures (as reflected by NIOSH-cohort exposure measures made starting in the late 1970s to which the NIOSH statistical regression model was fit), were in place prior to that time.

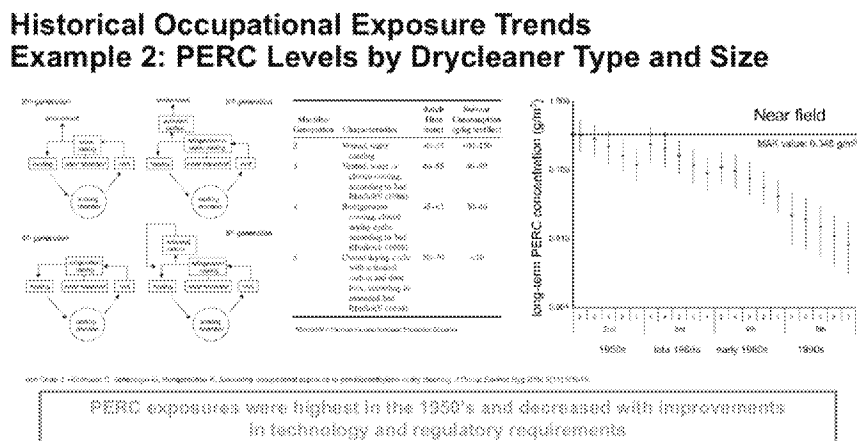
The pattern shown in Figure 1 indicates generally lower exposures for earlier time periods when the crudest technology was used under the least stringent worker protection standards. The SAB considered this pattern to be “surprising,” as discussed in greater detail in Section 4, below. Indeed, the pattern of the NIOSH exposure data by job in Figure 1 is the reverse of patterns of historical exposure levels from published studies of exposures to volatile chemicals through time with improvements in technology and increased worker protection requirements<sup>31</sup> as illustrated in two relevant examples (Figures 2 and 3).

### Historical Occupational Exposure Trends Example 1: TCE Levels by Degreaser Type and Size



**Figure 2.** Historical occupational exposure trends, Example 1: TCE levels by degreaser type and size. Source: von Grote et al. (2003b).

<sup>31</sup> E.g., von Grote JHM. 2003a. Occupational Exposure Assessment in Metal Degreasing and Dry Cleaning – Influences of Technology Innovation and Legislation. Doctoral Dissertation, Swiss Federal Institute of Technology, Zürich. Available at: <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.628.1123&rep=rep1&type=pdf>; von Grote J, Hürlimann C, Scheringer M, Hungerbühler K. 2003b. Reduction of occupational exposure to perchloroethylene and trichloroethylene in metal degreasing over the last 30 years: influences of technology innovation and legislation. *J Expo Anal Environ Epidemiol*, 13: 325-40; von Grote J, Hürlimann C, Scheringer M, Hunger K. 2006. Assessing occupational exposure to perchloroethylene in dry cleaning. *J Occup Envir Hyg*, 3: 606-19.



**Figure 3.** Historical occupational exposure trends, Example 2: PERC levels by dry cleaner type and size. Source: von Grote et al. (2006).

3. **The EO IRIS Assessment repeatedly asserts that the NIOSH exposure estimates were well-validated using a state-of-the art model, when in fact there was no validation of exposure estimates prior to 1978. These assertions regarding verification procedures are incorrect for the late 1930s to 1978.**

Assertions made in the EO IRIS Assessment about independent evaluation of model estimates are inaccurate. Table 1 lists the statements in the EO IRIS Assessment related to the UCC and NIOSH exposure assessments.

**Table 1:** List of EO IRIS Assessment statements regarding UCC or NIOSH exposure assessment

Page Number	Description of UCC exposure	Description of NIOSH exposure
1-1		Had a well-defined exposure assessment for individuals
1-2		“high-quality” study based on several attributes, including availability of individual worker exposure estimates from a high-quality exposure assessment
1-4		Retrospective exposure estimation is an inevitable source of uncertainty in this type of epidemiology study; however, the NIOSH investigators put extensive effort into addressing this issue by developing a state-of-the-art regression model to estimate unknown historical exposure levels using

Page Number	Description of UCC exposure	Description of NIOSH exposure
		variables, such as sterilizer size, for which historical data were available.
3-5	Crude exposure assessment, with a high potential for exposure misclassification	
3-6		... the exposure model and verification procedures are described in Greife et al. (1988) and Hornung et al. (1994). Briefly, a regression model was developed to allow estimation of exposure levels for time periods, facilities, and operations for which industrial hygiene data were unavailable. The data for the model consisted of 2,700 individual time-weighted exposure values for workers' personal breathing zones, acquired from 18 facilities between 1976 and 1985. The data were divided into two sets, one for developing the regression model and the second for testing it. Seven out of 23 independent variables tested for inclusion in the regression model were found to be significant predictors of EtO exposure and were included in the final model. This model predicted 85% of the variation in average EtO exposure levels.
3-7		Good-quality estimates of individual exposure
3-8	"cruder" especially for highest exposure	Based on a validated regression model
4-3 and 4-4	Exposure assessment is much less extensive than that used for the NIOSH cohort, with greater likelihood for exposure misclassification, especially in the earlier time periods when no measurements were available (1925-1973). Exposure estimation for the individual workers was based on a relatively crude exposure matrix that cross-classified three levels of exposure intensity with four time periods. The exposure estimates for 1974-1988 were based on measurements from air sampling at the West Virginia plants since 1976. The exposure	This is in contrast to the NIOSH exposure assessment in which exposure estimates were based on extensive sampling data and regression modeling. In addition, the sterilization processes used by the NIOSH cohort workers were fairly constant historically, unlike chemical production processes, which likely involved much higher and more variable exposure levels in the past.

Page Number	Description of UCC exposure	Description of NIOSH exposure
	estimates for 1957-1973 were based on measurements in a similar plant in Texas. The exposure estimates for 1940-1956 were based loosely on a “rough” estimate reported for chlorohydrin-based EtO production in a Swedish facility in the 1940s (Hogstedt et al., 1979). The exposure estimates for 1925-1939 were further conjectures based on the Swedish 1940s estimate. Thus, for the two earliest time periods (1925-1939 and 1940-1956) at least, the exposure estimates are highly uncertain. (See Section A.2.20 of Appendix A for a more detailed discussion of the exposure assessment for the UCC cohort.)	
4-5		It was judged to be substantially superior to the UCC study with respect to a number of key considerations in particular, in order of importance: (1) quality of the exposure estimates ...
4-60	largely uninformative in terms of assessing the unit risk estimates derived from the NIOSH study because of the crude exposure assessment used in the UCC study	

The EO IRIS Assessment does not critically evaluate the uncertainties of the NIOSH linear regression model, and does not clarify that the NIOSH model was not validated with any data prior to 1978. In the appendices, similar deficiencies pertain to assertions concerning measures applied purportedly to validate the NIOSH statistical regression model,<sup>32</sup> purported empirical and unbiased bases for the NIOSH statistical regression model,<sup>33</sup> and purportedly unlikely inaccurate characterization of exposure by the NIOSH statistical regression model and its purported validation despite nonexistence of original data upon which it was derived.<sup>34</sup>

NIOSH historical extrapolations of occupational EO exposures prior to the late-1970s, were, as described by Hornung et al. (1994), “derived from a regression model based on

<sup>32</sup> See EO IRIS Assessment, Appendix A, at A-14.

<sup>33</sup> See *id.*, Appendix D, at D-75.

<sup>34</sup> See *id.*, Appendix H, at H-27 – H-28.

observed measurements.” This regression model was applied to extrapolate worker exposures over a large timespan (1935-1975), during which not a single observed measurement was available to validate the application of that extrapolation procedure, and only a small subset of measures was available during 1976-77. Although the NIOSH statistical regression model reliably estimated exposure measurements made after 1977, Hornung et al. (1994) highlighted that post-1977 regulatory standards and consequent progressively stringent operational EO-exposure controls accounted for the pronounced decreasing trend in measured NIOSH-cohort EO exposures that occurred starting in 1978. Prior to 1978, EO standards and controls were largely or entirely absent. Thus, they were irrelevant to most of the 1935-1975 timespan.

4. **In response to public and SAB comments questioning the lower than expected exposures in earlier years predicted by the statistical regression model, the IRIS Program states that the decrease is related to the sterilizer volume. In other words, the model predicts that smaller sterilizer volume results in lower exposures. This response essentially uses the output of the model to answer a question about whether the model assumptions are correct, instead of independently verifying the validity of these assumptions. This circular reasoning does not address the underlying concern of whether the model assumption that Sterilizer Volume has an inverted parabolic (that is, an upside-down U-shaped) relationship with predicted EO exposure is correct. It also does not address whether other factors that might result in increased exposure during early years were properly accounted for in the model.**

During the review of the 2014 draft EO IRIS Assessment, the SAB questioned the general pattern of historical exposures that were lower in some or all years prior to 1975. The SAB had specifically requested EPA to address this issue in a substantive manner (i.e., using historical, physicochemical, and/or engineering facts or models independent of the NIOSH statistical regression model itself). The SAB noted:

The SAB is also concerned that public commenters had exposure data from the NIOSH cohort that the EPA did not have. For instance, a few selected graphs were presented in **public comments to the Augmented CAAC that indicated exposure predictions for four jobs in two of the fourteen plants showed lower exposures in some or all years prior to 1975. The SAB was provided only a few carefully selected examples, and thus was unable to assess the extent of these surprising data.** This is an uncertainty that can easily be ruled out. **Upon reviewing the model equation in Hornung et al. (1994), the SAB finds the surprising historical behavior to be unlikely** and could be explained by changes

in processes in specific plants, rather than some failure of the model to capture historically larger exposures. The EPA should ensure that they obtain all relevant data released from NIOSH to members of the public.<sup>35</sup>

Figure 1 above shows that the “surprising historical behavior” characterized by the SAB as “unlikely” does not pertain only to a few specific jobs in different plants, but is a general pattern going back in time prior to the late-1970s. EPA’s response to the SAB’s concern was:

contrary to public comments made at the SAB meeting, the NIOSH EtO exposure patterns are not anomalous, but rather reflect the underlying changes in variables predicting exposure over time. One of the principal drivers of the NIOSH exposure levels was the cubic feet of the sterilizers used [see Table III, Hornung et al. (1994)]. It was not uncommon in these plants for sterilizer volume to have increased over time as the demand for EtO-sterilized products increased.

**Increased sterilizer volume generally resulted in higher predicted average exposures until the late 1970s, when increased controls were used after it became known that EtO might be dangerous.**<sup>36</sup>

The IRIS Program provided quantitative examples illustrating the point emphasized in the quote above for two different plants, in effect illustrating that the response is consistent with the NIOSH statistical regression model defined in Tables III and VI of Hornung et al. (1994). However, the response is circular and, thus, nonresponsive to the SAB concern, because it relies on the same statistical regression model to attempt to validate its assertion that “increased sterilizer volume generally resulted in higher predicted average exposures until the late 1970s.”

The NIOSH regression model predicts that EO exposure levels are proportional to an inverted parabolic (upside-down U-shaped) function of sterilizer volume. This function reaches a maximum predicted EO exposure level at a sterilizer volume value of approximately 4,000 ft<sup>3</sup>. This regression function is estimated entirely from measurement data obtained nearly exclusively after 1977. However, NIOSH does not explain a plausible physical basis for this complex exposure/volume relationship observed nearly exclusively after 1977. Although this relationship explains a statistically significant amount of variation in the available EO measures, NIOSH offers no convincing evidence that such a relationship must also reliably apply to periods prior to 1978. Hornung et al. (1994) point out that regulatory constraints, sterilization operation, and

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<sup>35</sup> Science Advisory Board Review of the EPA’s Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (Revised External Review Draft - August 2014) (Aug. 7, 2015), EPA-SAB-15-012 (2015 SAB Review), at 18 (emphasis added).

<sup>36</sup> EO IRIS Assessment, Appendix I, at I-26 – I-27 (emphasis added).

sterilization technology all differed greatly from prior to 1978 vs. in/after 1978; they emphasize that in 1978, efforts to control EO exposure began to be implemented on an accelerated basis.

None of the three methods applied by Hornung et al. (1994) to validate their statistical regression model<sup>37</sup> is capable of providing any direct form of validation or verification of historical EO exposures actually incurred by the NIOSH cohort. The NIOSH regression model makes that prediction, based on its statistical regression fit to historical EO measurements that only began in the late 1970s, without any other empirical, physical-modeling, or engineering rationale upon which to establish even the plausibility of that model prediction (e.g., based on independent published literature, historical data, physical/compartamental modeling, or any type of reasoning whatsoever bearing on whether sterilizer chamber volume per se is or is not expected to have correlated with or determined historical EO exposure levels prior to the late-1970s).

Hornung et al. (1994) note that pounds of EO used each year served as a surrogate measure of potential EO exposure, but that since such EO utilization data “were not available for all plants in the study, the size of the sterilizer units (in cubic feet of capacity) was substituted after we determined that there was a high degree of correlation between these two variables.” However, in order to achieve sterilization efficacy, EO concentrations used in sterilization chambers have remained approximately constant over time—*regardless* of the volume of sterilization chambers used—except insofar as EO concentrations used are well known (and were reported by experienced EO industry workers in interviews discussed below) to have *increased* going backwards in time from the late 1970s, because higher concentrations of EO were used in earlier decades during the evolution of sterilization operations and technology.

Likewise, because utilization of internal sterilization chamber volume has remained fairly constant over time, independent of reduced chamber volume going back in time from the late 1970s, opening of each chamber door and storage of off-gassing sterilized materials resulted in similar immediate concentrations of EO exposure to nearby workers. Reduced chamber volumes going back in time implied that greater numbers of such smaller chambers had to be used to process approximately the same load of sterilized material per plant. To the extent that smaller amounts of sterilized material were processed by plants earlier in time, then those

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<sup>37</sup> Hornung et al. (1994) explain that, in the absence of historical exposure data to perform such verification, they applied a three-phase evaluation procedure consisting of 1) a statistical cross-validation procedure applied to a subset of post-1978 empirical measures of EO, 2) comparison of predictions made by “a panel of 11 industrial hygienists familiar with ethylene oxide levels in the sterilization industry” to the latter subset of empirical data gathered subsequent to 1978, and 3) an evaluation of the ability of the statistical model to explain the empirical variance exhibited by the entire set of empirical measures of (as noted above, nearly all post-1977) EO exposures available for the NIOSH cohort.

processes are certain to have occurred in smaller facilities, implying that going back in time since the late-1970s there was either an increase (as noted above) or no substantial change in the mass-of-EO-used to workspace-volume ratio that determined the time-weighted average EO concentration to which sterilization workers were exposed throughout that period (particularly for the most heavily exposed workers).

Of greater significance, EPA's response does not take into account critical variables, such as level of EO residue in sterilized materials based on the number of air washes used, the length of time sterilized materials were stored prior to return to customers, and where they were stored relative to chamber operations—variables that changed substantially over the decades of EO sterilization prior to the late 1970s. Historical (pre-late-1970s) estimates of NIOSH cohort EO exposure rely on historical extrapolations made only by the NIOSH statistical regression model that were driven primarily by a correlation primarily between chamber volume and post-late-1970s measures of EO exposure. Operational changes that could have influenced EO exposure concentrations prior to 1976/78 were not investigated.

Even the NIOSH study expected higher historical exposures that would be influenced by the absence of engineering and regulatory controls: "Exposure levels are likely to have been higher [than "the late 1970s"], however, before the installation of engineering controls, when the OSHA standard was 50 ppm instead of the present 1 ppm."<sup>38</sup> Moreover, in the 1940s and 1950s, the MAC-TWA and TLV-TWA were 100 ppm.<sup>39</sup> In 1978, the U.S. Food and Drug Administration (FDA) published proposed "maximum residue limits" of 5-250 ppm for medical devices for human use that are sterilized with EO. Prior to 1978, there were no regulatory standards to reduce residues on medical devices, so the residues were around 10–30,000 ppm depending on the type of material.<sup>40</sup> But the IRIS Program failed to take this information into account when modeling the data.

**5. The EO IRIS Assessment makes the unsubstantiated claim that "the sterilization processes used by the NIOSH cohort workers were fairly constant historically, unlike chemical production processes, which likely involved much higher and more variable exposure levels in the past."<sup>41</sup> In**

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<sup>38</sup> Steenland K, Stayner L, Greife A, Halperin W, Hayes R, Hornung R, Nowlin S. 1991. Mortality among workers exposed to ethylene oxide. *N Engl J Med*, 324(20): 1402-07, at 1406.

<sup>39</sup> ACGIH. 2001. Ethylene Oxide: TLV® Chemical Substances 7th Edition Documentation.

<sup>40</sup> Ernst RR and Whitbourne JE. 1971. Toxic residuals. In the Study of the requirements, preliminary concepts, and feasibility of a new system to process medical/surgical supplies in the field, pp. 46-57, Appendix pp. 1-2, Contract No. DADA17-70-C-0072. U.S. Army Medical R&D Command, Washington, D.C. (Defense Documentation Center Accession No. AD890320 and AD890321).

<sup>41</sup> EO IRIS Assessment, at 4-4.



**fact, there was an evolution in technology and practices associated with the sterilization processes between the late 1930s and early 1970s. Data and information from industrial sterilization operators and the literature refute this claim.**

Interviews conducted by Exponent, Inc. with three former sterilization operators who began work in the mid-1960s and early to mid-1970s (one was a member of the NIOSH cohort) confirmed operational differences in the sterilization operations in the 1960s and 1970s, and in earlier decades, relative to operations post-1978. This new interview information is supported by information and data in the technical literature on sterilization operations in early decades, including high EO residue levels in and rates of EO off-gassing from EO-sterilized medical materials,<sup>42</sup> and by current quantitative measures of in-chamber EO concentration during sterilization operations after single and multiple air washes that were transmitted to Exponent, Inc. by an industrial sterilization company. These data indicate that the EO IRIS Assessment's assumption that the sterilization processes were fairly constant between the late 1930s and early 1970s is incorrect.

These data also indicate that the variables in the NIOSH model that predicted exposures after the mid-1970s do not capture important potential sources of exposures to sterilizer operators prior to the 1970s:

- a. Technology improvements for worker protection such as back venting and use of aeration processing rooms to degas sterilized materials were implemented post 1978. Thus, the presence or absence of back venting or ventilated aeration rooms may help discriminate exposures after 1978, but not between the late 1930s and 1977.
- b. Pre-1978 commercial sterilization operations typically included at most only a single post sterilization air wash (relative to numerous washes used typically in later decades); in a current sterilization unit using 100% EO, an EO concentration

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<sup>42</sup> Perkins JJ. 1969. Principles and Methods of Sterilization in Health Sciences, 2nd ed. Charles C. Thomas, Springfield, IL; Bruch CW. 1972. Toxicity of ethylene oxide residues. In: Phillips GB, Miller WS, eds. Industrial sterilization, Duke University Press, Durham, NC, at 119-23; Bruch CW. 1981. Ethylene Oxide sterilization—technology and regulation. Industrial ethylene oxide sterilization of medical devices: process design, validation, routine sterilization, AAMI Technological Assessment. Report No. 1-81. Arlington, VA: Association for the Advancement of Medical Instrumentation, at 3-5; Roberts RB, Rendell-Baker L. 1972. Aeration after ethylene oxide sterilisation. Failure of repeated vacuum cycles to influence aeration time after ethylene oxide sterilisation. *Anesthesiol*, 27(3): 278-82; Stetson JB, Whitbourne JE, Eastman C. 1976. Ethylene oxide degassing of rubber and plastic materials. *Anesthesiol*, 44(2): 174-80; White JD. 1977. Standard aeration for gas-sterilized plastics. *J Hyg Camb*, 79: 225-32.

of 17,200 ppm was measured in chamber air after a single wash cycle. Fewer wash cycles result in much higher peak exposures when opening the chamber doors, as well as higher residue levels remaining on the pallets of sterilized material. These higher residue levels contribute to higher exposure levels to those working in areas where pallets are stored.

- c. Most 1960s and 1970s operations had evolved to storing the sterilized materials during degassing in a separate room from chamber operations, while operations in earlier decades had chamber operations and sterilized material stored in the same workspace. In the 1950s and 1960s, sterilizer operators would be expected to have higher exposures than in the 1970s because there was one (or no) air washes and the sterilized pallets with high residue levels were often stored in the same room as the chambers.
- d. Systematic application of forced and efficient ventilation where sterilizers were operating and where treated pallets were stored was rare or absent prior to the mid-1970s.
- e. The period of degassing of sterilized materials was generally about 7 days during the mid-1960s and 1970s, but was  $\leq 1$  day in earlier decades. This indicates that the levels of residues in the sterilized materials and, hence, exposures were consistently high in earlier decades.
- f. Although with increasing time prior to the mid-1970s sterilization operations involved smaller sterilizers (i.e., having smaller sterilizer chamber volumes), sterilizer operations involved less mechanized or non-mechanized processes, less- or non-ventilated chamber and storage operations, more leaky EO containment during sterilization, and more direct operator exposure to EO vapor (e.g., during change of filters contacting liquid EO and manual connection/disconnection of EO tanks)—factors that likely acted jointly to generate EO exposures to sterilizer operators and other related workers that were greater prior to the late 1970s than during later periods.
- g. According to interviewed operators with decades of experience in the EO sterilization industry, concentrations of EO applied in sterilizers currently and since the late 1970s (400–600 mg/L) have been lower by a factor of roughly 1.5 than those applied during earlier decades, and resulting chamber concentrations of EO upon opening of sterilizer chamber doors (which at that time were not actively

ventilated) thus are likely to have been equal to or (with increasing likelihood going back further in time) greater than those that occurred during 1978.

Each of these factors taken alone or in combination indicate that, compared to the sterilization worker environment starting in 1978, when technology improvements and regulatory controls were introduced with increasing frequency and stringency, it is highly probable that greater EO concentrations occurred in the sterilization worker environment from the mid-1960s to the late 1970s. Moreover, it is virtually certain that even greater EO concentrations occurred in the sterilization worker environment prior to the mid-1960s, contrary to trends in occupational exposures during those times that were extrapolated using the NIOSH statistical regression model.

The new information summarized above confirms that the SAB's concern was not effectively addressed by the IRIS Program, and therefore all assessments of EO cancer risk derived using NIOSH epidemiological study data are potentially confounded by greater magnitudes of uncertainty than are stated in the EO IRIS Assessment. These assessments are based on historical extrapolations of occupational exposures prior to the late-1970s produced by the NIOSH regression model and thus necessarily depend on the accuracy and reliability of those extrapolations. This major source of uncertainty in the EO IRIS Assessment is a key defect.

- 6. Comparisons of relative reliability made between the NIOSH and UCC studies are inaccurate. These comparisons were a key basis upon which the IRIS Program rejected the UCC Study as a source of epidemiology study data for cancer risk assessment. The EO IRIS Assessment does not acknowledge and appropriately consider limitations of the NIOSH exposure assessment posed by low extrapolations of NIOSH cohort exposures to EO prior to the late 1970s without any corroborating data or any supporting engineering/process considerations derived from or directly relevant to that period of time.**

The EO IRIS Assessment argues inaccurately that the UCC exposure assessment was “too crude” to be used for exposure-response analysis (see Table 1). To the contrary, Greenberg et al. (1990) describe their categorization of departments into “high,” “medium,” and “low” categories based on a detailed reconstruction of processes using records and interviews of older employees.<sup>43</sup> The categorization was validated using frequencies of visits to the medical department for acute over exposures. The UCC exposure assessment was expanded to include

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<sup>43</sup> Greenberg HL, Ott MG, Shore RE. 1990. Men assigned to ethylene oxide production or other ethylene oxide related chemical manufacturing: A mortality study. *Br J Ind Med*, 47: 221-30.

individual exposure estimates, as described in detail by Swaen et al. (2009).<sup>44</sup> All such efforts associated with epidemiology studies require assumptions and involve uncertainties.

The UCC study, however, includes actual UCC data based on monitoring data from the UCC Texas plant with very similar operations from as early as 1957. Estimates for the 1940-1956 period are based on the published literature for companies using a similar process for EO production. The greatest uncertainty is for 1925-39; however, only 4.8% of the cohort worked during that period. In contrast, **approximately 70% of the NIOSH cohort had workplace exposures prior to 1978, the period of unverified exposure estimates.**

The EO IRIS Assessment's criticism of the UCC approach, i.e., it includes data from a comparable plant that was not part of the cohort, is biased because NIOSH also used exposure data from plants that were not included in the cohort. The fact that UCC-cohort exposures estimated between 1957-1973 are based on contemporary actual exposure measurements obtained from a very similar plant is a major advantage (and certainly not a deficiency) of the UCC approach relative to the NIOSH study.

In contrast, critical limitations and uncertainties associated with NIOSH's statistical regression modeling for the period prior to the late 1970s (based entirely on a fit obtained to data gathered only starting in the late 1970s, since no actual measurements of EO exposure were available for the NIOSH cohort prior to that time) are not accurately characterized or even meaningfully acknowledged in the EO IRIS Assessment or in related NIOSH publications. For example, Hornung et al. (1994) did not reveal that their approach resulted in lower, rather than higher, exposures over the entire period addressed prior to the late 1970s, with no exposures prior to 1978 exceeding those that occurred in and also were reliably estimated for 1978. As noted above, the pattern predicted by the NIOSH statistical regression model conflicts with what is known about early processes in the sterilant industry, and was characterized as "surprising" and "unrealistic" by the SAB.

The EO IRIS Assessment is highly misleading because what it refers to as NIOSH statistical regression model "validation" was done only for its post-late-1970s predictions, since no earlier EO-measurement data were available. Model extrapolations of historical EO exposure prior to the late 1970s were conjectural, relying entirely on putative explanatory power of a regression model fit to EO-measurement data that, as acknowledged by Hornung et al. (1994), exhibited a steeply declining pattern of EO exposures over time post-1977 due to regulatory concerns and EO-control measures that simply did not exist previously. New information

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<sup>44</sup> Swaen GM, Burns C, Teta JM, Bodner K, Keenan D, Bodnar CM. 2009. Mortality study update of ethylene oxide workers in chemical manufacturing: a 15 year update. *J Occup Environ Med*, 51(6): 714-23.

described above confirms that the NIOSH exposure estimates for periods prior to the late 1970s are substantially and unrealistically low, and therefore are likely to have biased all assessments of EO cancer risk that relied only on NIOSH cohort study data. Moreover, the IRIS Program has failed to investigate whether such bias may render assessments of EO cancer risk unreliable.

- 7. The EO IRIS Assessment relies solely on the NIOSH study of sterilant workers and fails to incorporate the important findings from the UCC study of workers in EO producing and using operations. The IRIS Program considered and characterized three factors in its selection of the NIOSH study: cohort size, exposure data, and confounding. Based on these factors, the IRIS Program dismissed the UCC study as a basis for EO cancer risk estimation. In considering cohort size, the IRIS Program ignored the most important comparison—the number of lymphohematopoietic tissue cancers, not the total cohort size.**

As discussed in detail in the other sections, the NIOSH study does not have superior exposure data compared to the UCC study, so both studies have comparable applicability to risk assessment.

Cohort size is only one factor in assessing study informativeness. The most important factor is the number of events of interest, which for a mortality study is dependent on length of follow up and percent deceased. The most recent published study of the UCC cohort reports a sizeable number of deaths due to leukemia and lymphomas, comparable to the events among males in the NIOSH study that would make a meaningful contribution to the number of events for an exposure-response analysis.<sup>45</sup> Despite the smaller number of male workers in the UCC study, they have been followed for a longer period of time (37 yr on average compared to 25 yr for the NIOSH study) and include 51% deceased compared to 19% of the much younger NIOSH sterilant population. The EO IRIS Assessment criticizes the sample size in the UCC cohort, noting (erroneously) “only” 27 LHC cancers and 12 leukemias; the correct number of leukemias is 11 (EPA interchanged the numbers of leukemia and NHL deaths). However, the EO IRIS Assessment does not also note the male population of the NIOSH study had 37 LHC cancers and only 10 leukemias. Furthermore, no substantive criticisms of the NIOSH study appear in the EO IRIS Assessment, when in fact there are major uncertainties with respect to the NIOSH exposure estimates as described in detail above.

The EO IRIS Assessment raises concerns about confounding in the UCC study because of the presence of multiple chemicals in the workplace. This source of bias would only be

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<sup>45</sup> Swaen et al. (2009).

expected when analyses yield positive findings, i.e., increases that may not be attributed to EO but to other chemicals. This, in fact, was identified by Greenberg et al. (1990), which reported an increase in leukemia and pancreatic cancer that was found to be attributable to exposures to one or more chemicals in the ethylene chlorohydrin production unit that was characterized as a “low” EO department. The 278 workers involved in that department were removed from the cohort and separately analyzed in a companion publication,<sup>46</sup> which verified increased risk observed by Greenberg et al. (1990). The remaining EO workers did not exhibit cancer increases in subsequent updates.<sup>47</sup> The three central reasons cited in the EO IRIS Assessment for excluding the UCC study are not defensible as explained above, and therefore indicate a biased preference for using the NIOSH study as a sole basis for EO cancer risk estimation.

In addition, the EO IRIS Assessment diminishes the value of the most recent UCC cohort study claiming they were followed so long that background rates of lymphoid tumors would be so large as to miss increased risks due to EO. The important factor is to have sufficient time since first exposure (latency). The 37 yr. average follow-up of Swaen et al. (2003) is not excessive in light of the fact that the most recent hires (1988) have 15 yr. follow-up at most. It is desirable to have 20-25 yr. follow-up for a cancer outcome of interest and even longer when exposures are lower as they were post-1976. Furthermore, there were two earlier studies of this cohort (Greenberg et al., 1990 and Teta et al., 1993) when the cohort was younger, which failed to identify EO-related cancer increases. These studies examined the findings by hire date, duration of exposure, time since first exposure and performed comparisons to the non-exposed chemical workers adjusting for age. It is implausible and speculative that the aging of the cohort masked significant EO-related cancer increases.

The UCC study should have been incorporated in both the hazard characterization and the exposure-response analysis. Consequently, the IRIS Program’s handling of these key issues—cohort size, exposure estimation, and confounding—is incomplete, inaccurate, and biased.

- 8. The use of the supralinear spline model for the lymphoid and breast cancers in the final EO IRIS Assessment is based on an invalid statistical analysis. Because the analysis did not correctly calculate degrees of freedom associated with that fitted model, it contains erroneous measures of absolute and relative goodness of fit of that model. When both the p-values and Akaike**

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<sup>46</sup> Benson LO, Teta MJ. 1993. Mortality due to pancreatic and lymphopoietic cancers in chlorohydrin production workers. *Br J Ind Med*, 50: 710-16.

<sup>47</sup> Teta MJ, Benson LO, Vitale JN. 1993. Mortality study of ethylene oxide workers in chemical manufacturing: A 10 year update. *Br J Ind Med*, 50: 704-09; Swaen et al. (2009).

**Information Criterion (AIC) values characterizing fit quality are corrected, the supralinear spline model does not fit the NIOSH lymphoid tumor data statistically significantly better than the log-linear Cox model.**

The EO IRIS Assessment justifies why it does not account for the degrees of freedom by citing the 2015 SAB Review: “The knot is preselected and is not considered a parameter in these analyses, consistent with the SAB’s concept of parsimony (SAB, 2015).”<sup>48</sup> However, the concept of parsimony is a preference for a simpler model with fewer estimated parameters when fitting and evaluating a single model. The SAB did not direct EPA to violate well founded and widely accepted statistical practice by ignoring the fact that a particular parameter (in this case, the knot of a bi-linear spline model) of a spline model was actually estimated when defining the total number of its estimated parameters, when comparing the goodness of fit of that spline model to another model (such as a log-linear model) that involves no estimated knot.<sup>49</sup>

The EO IRIS Assessment indicates to fit particular supralinear spline models, their “knots were obtained by doing a grid search by increments of 100 ppm x days and then interpolating where appropriate.”<sup>50</sup> In other words, the knot of the final supralinear spline model selected was indeed an additional estimated (in this case, numerically optimized) parameter, standard statistical model-fitting procedures always require that p-values be evaluated for a goodness-of-fit statistic only after subtracting one degree of freedom *for each one of the total number of parameters (a number typically denoted as  $k$ ) that are estimated when fitting a model*, regardless of how such parameters are estimated.

Failure to follow this procedure always results in an erroneously inflated “p-value” for goodness of fit (only a model with a p-value for goodness-of-fit larger than 0.05 is typically considered acceptable), and thus also in an underestimated value of a corresponding AIC used to compare goodness of fit of different models (a model with a smaller AIC value is preferred, and AIC is defined as twice the sum of  $k$  [defined above] and a fit-specific positive quantity). If the proper procedure is not followed to define total degrees of freedom ( $k$ ), the result is a p-value indicating a fit that is better than actually is the case (i.e., a p-value indicating that deviations between a fitted model and the observed/modeled data are more likely to have occurred by chance alone than actually is the case), and consequently also an AIC value that misrepresents a

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<sup>48</sup> EO IRIS Assessment, Appendix D, at D-6.

<sup>49</sup> The EO IRIS Assessment quotes the SAB as follows: “in some settings the principle of parsimony may suggest that the most informative analysis will rely upon fixing some parameters rather than estimating them from the data. The impact of the fixed parameter choices can be evaluated in sensitivity analyses. In the draft assessment, fixing the knot when estimating linear spline model fits from relative risk regressions is one such example.” Appendix D, at D-6, note 11.

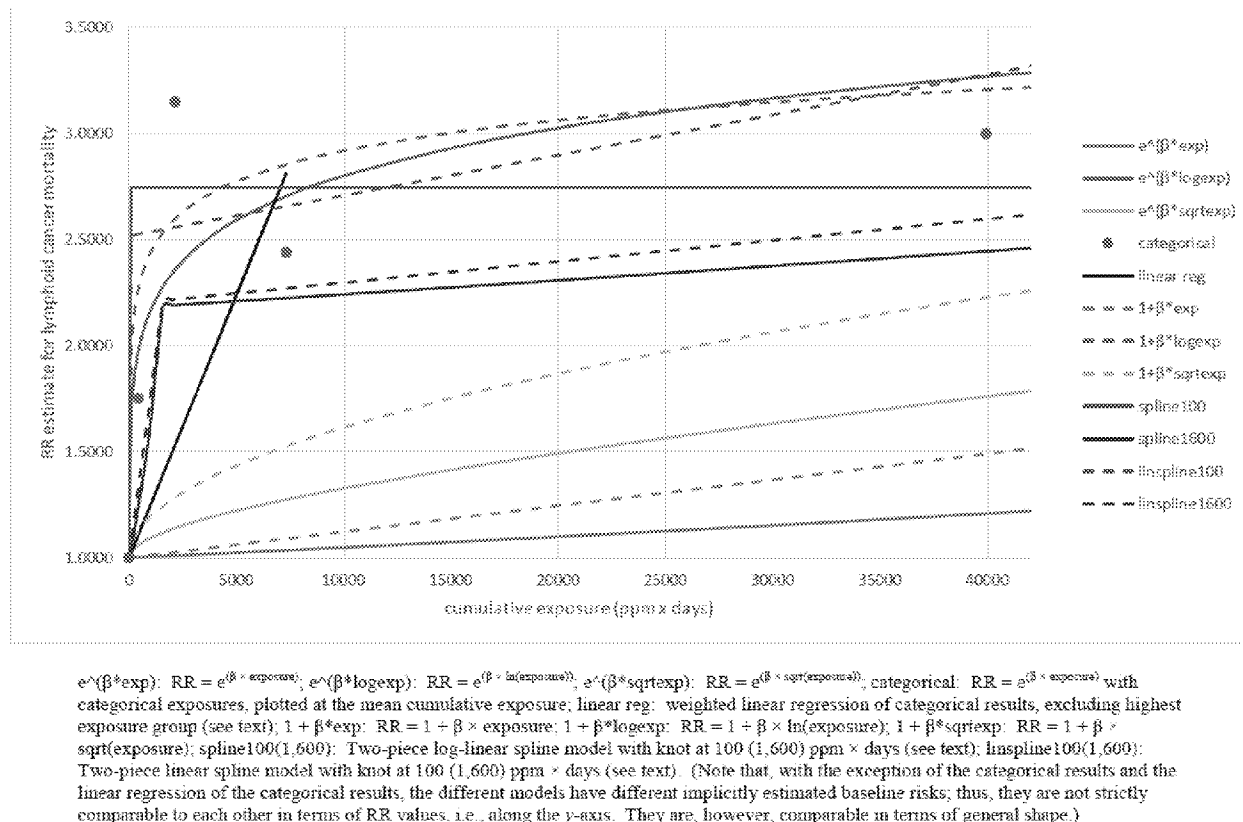
<sup>50</sup> EO IRIS Assessment, Appendix D, Table D-27, note a.

model's goodness of fit relative to that of another model for which degrees of freedom ( $k$ ) are defined properly.

By ignoring this statistical procedure for its supralinear spline model fit, the EO IRIS Assessment artificially and erroneously inflates the p-value and reduces the AIC value that was used to compare that model to those of other models being compared for which degrees of freedom were defined correctly. **When both the p-values and AIC values are corrected, the selected supralinear spline model does not fit the NIOSH lymphoid tumor data statistically significantly better than the log-linear cumulative model (see Appendix 1).**

9. **The selection of the supralinear spline model for the lymphoid tumors is also based on misleading illustrations of “visual fits” that do not convey either the actual data that were fit or the relative goodness of fit to these data of log-linear and supralinear spline models. Only in a footnote does the IRIS Program acknowledge that the visual comparison misrepresents the log-linear model being compared. Consequently, and erroneously, the fit to the data appears far worse than the supralinear spline model. The data plotted in that figure also were summary data that misrepresent the true magnitude of the scatter of the data that were used for model fitting.**

The EO IRIS Assessment visually represents alternative models considered in relation to data used for model fitting in Figures 4-3 through 4-8, explaining that “to facilitate a visual comparison of the models, select models are replotted against the categorical data in deciles.” Figure 4 below reprints Figure 4-3 from the EO IRIS Assessment and illustrates the incorrect basis for the conclusion that the NIOSH exposure-response is supralinear and that only models that are supralinear have good visual fit to the data.



Source: Steenland reanalyses for males and females combined; see Appendix D (except for linear regression of categorical results, which was done by EPA).

**Figure 4-3. Exposure-response models for lymphoid cancer mortality vs. occupational cumulative exposure (with 15-year lag).**

**Figure 4.** Figure 4-3 from the EO IRIS Assessment using categorical data (solid purple points) to compare the visual fits of the different models, including the selected two-piece log-linear-spline model (dashed red curve) and the standard Cox log-linear regression model (solid blue curve).

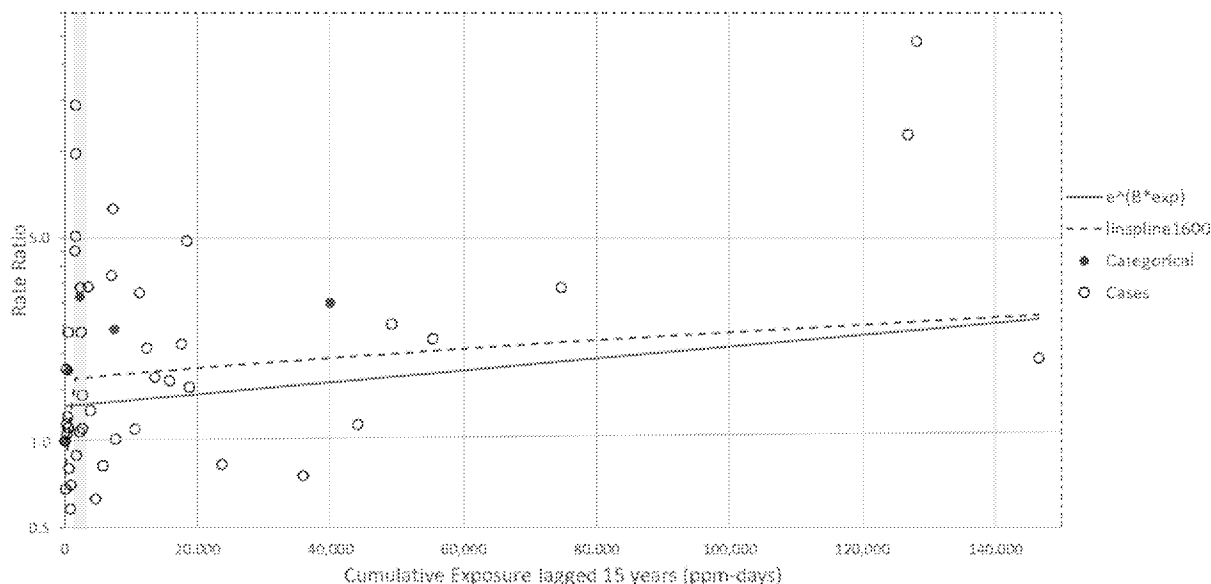
Figure 4-3 misrepresents the relative quality of true visual fits to the EO IRIS Assessment's preferred supralinear spline model compared to the more parsimonious log-linear Cox regression model in two important ways. First, Figure 4-3 plots data points that represent categorical data aggregated into quartiles (filled purple points in Figure 4, above) instead of the actual individual cases modeled. This comparison was used in earlier drafts of the IRIS Assessment when the 2014 draft EO IRIS Assessment modeled those categorical aggregated or summary data. However, when the final EO IRIS Assessment followed the SAB's recommendation to model individual cases, the data plots were not corrected accordingly to show the true magnitude of data scatter in relation to fitted models.

Second, the IRIS Program acknowledges in a footnote to Figure 4-3 that “the various models have different implicitly estimated baseline risks; thus, they are not strictly comparable to each other in terms of RR values (i.e. along the y-axis). They are, however, comparable in terms of general shape.” It is not transparent, however, that these graphs cannot be used at all to compare some of the models shown in a valid way. In particular, the lower log-linear model fit shown (the solid blue “line” that appears to go through the origin of the plot shown in Figure 4-3) appears to provide a very poor fit to the cloud of individual data through which that model passes, because the place where that model is shown to intersect the y-axis was artificially forced (in that figure) to intersect the value of 1 along the y-axis, when in fact that model does actually pass centrally through the cloud of actual raw data to which it was fit. That is, although both the EO IRIS Assessment’s preferred model and the log-linear model do more or less centrally pass through the cloud of data to which these models were fit, Figure 4-3 misleads the reader by showing a relatively poor fit of the simpler (i.e., more parsimonious) log-linear model compared to the more complex supralinear spline model that was selected in the EO IRIS Assessment.

Figure 5<sup>51</sup> more accurately compares the supralinear spline model (red dashed curve) and the standard Cox log-linear regression model (solid blue curve). The latter model is the approach used by Valdez-Flores et al. (2010) to fit the NIOSH, UCC, and combined NIOSH+UCC study data for lymphoid tumors. In Figure 5, the baseline (zero-exposure) value of hazard rate (HR) to which the log-linear model was fit is set equal to the same baseline HR as that estimated using the supralinear spline model. Therefore, Figure 5 shows more accurately than Figure 4 that the supralinear spline model fits the data no better than standard Cox log-linear regression model.

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<sup>51</sup> Figure 5 improves comparison along the y-axis by dividing model-estimated values of hazard rate (HR) ratio by the baseline HR of the individual categorical cases (thus making an apples-to-apples comparison), and uses a logarithmic scale to improve comparison of the linear difference between the fitted models and observed values of relative risk measured as hazard rate ratio (RR). In Figure 4, RR values greater than one appear disproportionately more distant from 1 than RR values less than one, because of the linear RR scale used in that figure. RR values greater than one can be as large as infinity, but RR values less than one cannot be less than 0. In contrast, values of  $\text{Ln}(\text{RR})$ —i.e., values of RR plotted on a logarithmic scale—as shown in Figure 5 can be as large as infinity and as small as minus infinity (see Appendix 1).



**Figure 5.** Apples-to-apples comparison of the EO IRIS Assessment’s preferred supralinear spline model (red dashed curve) and the log-linear Cox proportional hazards model (solid blue curve), plotted in relation to categorical data (solid purple points) from Figure 4 together with corresponding actual (raw/individual-level) data to which these models were fit (open points).

The misleading plots of categorical data in the EO IRIS Assessment were a key justification for its rejection of the standard Cox log-linear proportional hazards model in favor of a supralinear exposure-response relationship, as indicated in Table 4-14 of the EO IRIS Assessment.

- 10. The selection of a spline model as the preferred model for EO cancer risk estimation assumes a supralinear increase in tumor response in the low-dose exposure region with a subsequent plateauing of response at higher exposures. The body of cancer epidemiologic studies, including the NIOSH studies, does not support such a pattern of risk. While certain NIOSH sub-analyses suggest increases in male lymphoid tumors and female breast cancers, the findings are limited to the highest cumulative exposure groups, not the lowest.**

Steenland et al. (2003) state, “Exposure-response data do suggest an increased risk ... for those with higher cumulative exposures to ETO.”<sup>52</sup> The authors also say, “The dip in the spline

<sup>52</sup> Steenland K, Whelan E, Deddens J, Stayner L, Ward E. 2003. Ethylene oxide and breast cancer incidence in a cohort study of 7576 women (United States). *Cancer Causes Control*, 14: 531-39.

curve in the region of higher exposures suggested an inconsistent or non-monotonic risk with increasing exposure.” The default expectation for a genotoxic carcinogen would be this pattern of monotonically increasing risk in relation to exposure, which is why the authors call it “inconsistent.” The EO IRIS Assessment notes that it is not unexpected to have fluctuations in exposure-response curves due to random variation, yet in the exposure-response section the IRIS Program models such plausibly random fluctuation using a supralinear response model.

The EO IRIS Assessment cites Mikoczy et al. (2011)<sup>53</sup> to support the use of the supralinear spline model for breast cancer: “Although the reason for the observed supralinear exposure-response relationship is unknown, it is worth noting that the results of the Swedish sterilizer worker study reported by Mikoczy et al. 2011, ...support the general supralinear exposure-response relationship observed in the NIOSH study.”<sup>54</sup> However, Mikoczy et al. (2011) studied a low-exposure population that exhibited a significant increase in breast cancer incidence only when analyzed using an internal analysis comparing more-highly exposed to low-exposed workers, and exhibited no such significant increase in a corresponding external analysis involving comparison to matching members of a general population. The explanation for this anomaly lies in the dramatic and (as indicated by Mikoczy et al., 2011) statistically significant deficit of breast cancers in the low exposure group of the internal comparison; because in the internal comparison that low-exposed group was used as the referent group, the two higher exposure groups being compared showed significantly higher rates breast cancer relative to that lower-exposed group.

It might be argued that the non-representative and significantly low rate of breast cancer incidence exhibited by the low-exposure group used for internal comparison simply reflects a Healthy Worker Effect (HWE). However, the breast cancer rate for that group was remarkably low (only about half that of the reference population group of age-matched Swedish women used), and there is no HWE specific to breast (or to any other type of) cancer in Swedish female workers.<sup>55</sup> Thus, the EO IRIS Assessment does not accurately acknowledge and address the problematic nature of the internal-comparison reference group that served as the basis for results of internal comparisons of breast cancer incidence reported by Mikoczy et al. (2011).

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<sup>53</sup> Mikoczy Z, Tinnerberg H, Jonas Björk J, Albin M. 2011. Cancer incidence and mortality in Swedish sterilant workers exposed to ethylene oxide: updated cohort study findings 1972–2006. *Int J Environ Res Public Health*, 8: 2009-19.

<sup>54</sup> EO IRIS Assessment, at 4-71.

<sup>55</sup> Gridley G, Nyren O, Dosemeci M, Moradi T, Adami HO, Carroll L, Zahm SH. 1999. Is there a healthy worker effect for cancer incidence among women in Sweden? *Am J Ind Med*, 36(1): 193-99.

The EO IRIS Assessment's extra risk estimate suggests a highly potent carcinogen. This is contrary to epidemiology findings which show overall weak positive findings (see Appendix 2). While interest has centered on leukemia, other blood related malignancies, and recently on breast cancer, there are numerous inconsistencies among the studies; elevated risks above background, in isolated studies, are of small magnitude; and there is an absence of a clear exposure-response for any specific cancer type. The most informative studies are the NIOSH (Steenland et al. 2003, 2004) and UCC studies (Swaen et al. 2009), which are studies of comparable utility for risk assessment purposes. These epidemiology studies do not support supralinearity (high risk at low exposures). Certain NIOSH subanalyses showed increase for males only (lymphoid tumors) in the highest (not the lowest) cumulative exposure groups. Extended follow up of chemical workers, UCC and others, and sterilant workers show little, if any, increases. The epidemiological evidence does not support the RSC of 0.1 ppt, which suggests a highly potent carcinogen.

- 11. The use of a supralinear spline model for cancer risk estimation is inconsistent with the assumed mode-of-action of EO toxicity and tumorigenicity. Such a model predicts higher risk at low exposures compared to risks predicted at higher exposures, which is contradicted by the well-understood mode of action of EO in experimental animals and humans as described in the EO IRIS Assessment. Thus, the EO IRIS Assessment relies on human cancer risk estimates based on spline-model dose-response extrapolations that are internally inconsistent with its own evaluation of the mode of action of EO. The mean air concentration equivalent to the endogenous concentration in non-smoking humans with no known EO exposures is 1.9 ppb (range 0.13-6.9 ppb; continuous), which is 19,000 times greater than the EO IRIS RSC of 0.1 ppt. An alternative LEC (1/million) of 0.5-1.2 ppb is a more pragmatic, science-based approach for EO risk assessment.**

As a direct acting DNA- and protein-reactive toxicant, the high-level toxicological and cancer mode of action of EO importantly predicts a *sublinear* increase in dose-response at low exposures and an associated dose-disproportionate *increase* in toxicity at higher EO doses.<sup>56</sup> This expected dose-response pattern is due to attenuation of low-dose EO toxicity mediated by intervention of key detoxification pathways (EO conjugation with glutathione and enzymatic hydrolysis to oxidized metabolites; repair of EO-induced DNA adducts), and an associated dose-disproportionate (supralinear) increase in toxicity at higher doses due to saturation of those same pathway(s) as the EO dose increases, as summarized below in Figure 6.

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<sup>56</sup> Kirman and Hays (2017).

The EO IRIS Assessment describes and supports this projected EO mode of action and its implications for the shape of the cancer dose response in the low- to high-dose regions as follows:

[E]PA considers it *highly plausible that the dose-response relationship over the endogenous range is sublinear* (e.g., that the baseline levels of DNA repair enzymes and other protective systems evolved to deal with endogenous DNA damage would work more effectively for lower levels of endogenous adducts), that is, that the *slope of the dose-response relationship for risk per adduct would increase* as the level of endogenous adducts increases.<sup>57</sup>

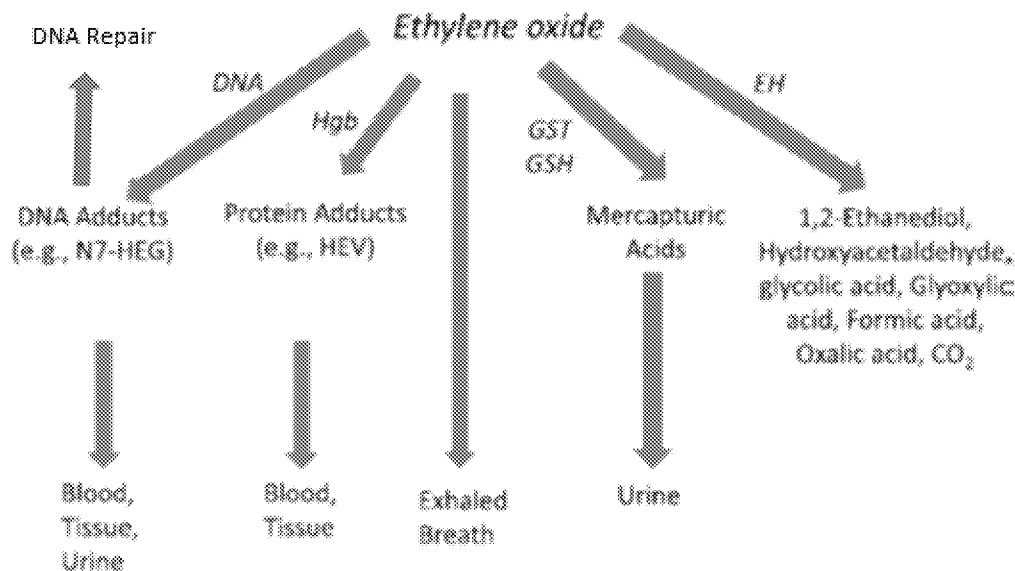
The EO IRIS Assessment’s analysis of the EO mode of action emphasizes that the dose-response is highly likely (“highly plausible”) to be *sublinear* “over the endogenous range” of internal EO doses that result from well-characterized endogenous production of EO secondary to metabolism of ethylene originating from normal biological processes.

Exploiting the well-defined linear relationship between exogenous EO exposure and systemic hemoglobin adducts in humans, Kirman and Hays (2017) estimate that the contribution of endogenously generated EO exposures to the overall systemic dose of EO is substantially greater than the 0.1 ppt exogenous EO exposure projected by the EO IRIS Assessment as resulting in a  $1 \times 10^{-6}$  cancer risk in humans. A meta-analysis of 661 non-smoking individuals not exposed to external EO indicated that endogenous background EO exposures are equivalent to a mean external exogenous EO exposure of 1.9 ppb (range 0.13-6.9 ppb). This “endogenous equivalent” contribution to the overall systemic EO dose is 19,000 times greater than the 0.1 ppt exogenous EO one-in-a-million risk dose estimated by the EO IRIS Assessment.

It is clear that even a 1000-fold increase in exogenous EO exposures above 0.1 ppt would only approach the low end of the total systemic EO dose contributed by endogenous EO generation. Any contributions of exogenous EO to cancer risk below this low-end endogenous dose would not be detectable within the likely day-by-day intra- and inter-individual variability (0.13-6.9 ppb) associated with normal endogenous EO exposure loads.

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<sup>57</sup> EO IRIS Assessment, at 4-95 (emphasis added).



Modified from Kirman & Hays, Reg Toxicol Pharmacol 91: 165-172, 2017

**Figure 6.** EO metabolism (adapted from Kirman and Hays, 2017).

Kirman and Hays (2017) also recognize that increased EO hemoglobin adducts associated with smoking provided an opportunity to further check the EO IRIS Assessment's supralinear model predictions that moderately low external EO exposures realistically contribute to increased cancer risks. A meta-analysis of 379 smokers not otherwise exposed to EO found that smoking increased EO exposures approximately 10-fold above the endogenous equivalent dose for background (non-EO exposed) individuals (mean background endogenous equivalent exposure = 1.9 ppb; mean smoker exposure = 18.8 ppb). The spline-model relied on by the EO IRIS Assessment predicts that the moderate increase in EO exposure associated with smoking would result in a detectable increase in lymphohematopoietic and breast cancers. However, this expectation is not met despite the very large smoking cohort.

Kirman and Hays (2017) note that smoking has been causally associated only with one subtype of lymphohematopoietic cancer, acute myeloid leukemia (AML). Not only is this cancer not increased in the NIOSH occupational cohort specifically exposed to higher doses of EO than those resulting from smoking, but Valdez-Flores et al. (2010), using a non-spline-based risk model, also demonstrate a statistically significant negative slope between cumulative exposure to EO and AML in that same NIOSH cohort. Kirman and Hays (2017) also observe that evidence

of a causal relationship between smoking and breast cancer is considered only as suggestive and not sufficient. Thus, projections of low-dose elevations in specific EO-associated cancer risks based on spline model extrapolations from relatively high occupationally-exposed individuals are not consistent with cancer outcomes in the much larger smoking cohort experiencing moderately elevated EO exposures.

Kirman and Hays (2017) also address the concern that any additional exogenous EO exposures above background, regardless of how small, represent a plausible contribution to increased cancer risks. They conclude that the approximate four order of magnitude disparity between EO endogenous exposures (mean = 1.9 ppb) and EPA projected increased risk at exposures greater than 0.1 ppt “creates a signal-to-noise issue [in the biological plausibility of tumor outcomes] when exogenous exposures fall well below those consistent with endogenous exposures. In such cases, small exogenous exposures may not contribute to total exposure or to potential effects in a biologically meaningful way.”

Recently, Calabrese (2018)<sup>58</sup> offers additional insight into the lack of plausibility of additivity to background of risks associated with low (and particularly less than background) exposures to EO. Calabrese reports that the mutational spectra of K-ras in EO-induced lung and Harderian gland tumors, and H-ras and p53 in mouse mammary tumors, were not at all similar to mutational spectra of these same tumors in control mice from the EO studies. These molecular-level data indicate that the mode of action of generation of control (background) tumors differs substantively from those originating from exogenous EO-exposed animals, even though control animals experience significant endogenous EO exposures. Thus, these data stand in contrast to the assumption of additivity to background that presumes that chemically-induced elevation of background tumors that are otherwise pathologically similar to chemically-induced tumors must share common mode(s) of action reviewed by Calabrese (2018).

The potential for additivity to background also is not supported by a comparison of total endogenous EO-specific DNA adducts in spleen, liver and stomach of rats relative to adducts in these same tissues resulting from a thousand-fold range of EO intraperitoneal doses (0.0001, 0.0005, 0.001, 0.005, 0.01, 0.05 and 0.1 mg/kg/day; 0.1 mg/kg/day approximately equivalent to a 1 ppm 6 hr/day EO inhalation exposure).<sup>59</sup> Importantly, Marsden et al. (2009) also emphasize that the increase in adducts associated with exogenous EO were not statistically significant at any

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<sup>58</sup> Calabrese EJ. 2018. The additive to background assumption in cancer risk assessment: A reappraisal. *Envir Res*, 16: 175-204.

<sup>59</sup> Marsden DA, Jones DJ, Britton RG, Ognibene T, Ubick E, Johnson GE, Farmer PB, Brown K. 2009. Dose-response relationships for N7-(2-hydroxyethyl)guanine induced by low-dose [<sup>14</sup>C]ethylene oxide: evidence for a novel mechanism of endogenous adduct formation. *Cancer Res*, 69(7): 3052-59.

dose with the exception of adducts in liver in rats administered 0.05 mg/kg/day, suggesting that exogenous adducts may not present any additional risk over endogenous adducts over this range of EO doses (i.e., additivity to background). Interestingly, endogenous DNA adducts were statistically increased in spleen and liver at the 0.05 and 0.1 mg/kg/day EO, indicating that higher EO doses alter internal biological processes leading to increased potential for endogenous EO formation.

Further investigations demonstrated that the high-dose-specific in endogenous-only adducts may have been secondary to increased oxidative stress. Both the high level of background endogenous adducts and high-dose specific increases in endogenous-only EO adducts further supports the authors' conclusion that "if the compound [EO] is produced endogenously, low doses of exogenous exposure may be overwhelmed by the background levels, leading to no detectable statistically significant increase in risk due to the external exposure." This conclusion (see Figure 6) is entirely consistent with the analyses developed by Kirman and Hays (2017) in which endogenous EO equivalent exposures in humans (mean = 1.9 ppb) are estimated as being 19,000 times higher than the exogenous EO dose of 0.1 ppt presenting a one-in-a-million cancer risk from spline-model low-dose extrapolation.

An alternative LEC (1/million) of 0.5-1.2 ppb is within the range of endogenous EO levels. Taking into account the biological mode of action and the endogenous EO equivalent exposures in humans, this approach is more plausible and science-based than the EO IRIS assessment.

- 12. The statistical, epidemiological and biological evidence does not support the selection of supralinear spline models to fit the NIOSH study data in the EO IRIS Assessment. A more scientifically sound conservative alternative is to use the Valdez-Flores et al. (2010) approach, which incorporates all the available data from the two strongest human studies (NIOSH and UCC). This approach has been adopted by the Scientific Committee on Occupational Exposure Limits.**

As described in previous sections, the selection of the supralinear spline model is based on incorrect statistical analysis and biased evaluation of the NIOSH exposure modeling relative to the UCC exposure estimates. Furthermore, the epidemiological evidence and biological mode of action do not support the supralinear spline model. A more scientifically supportable approach is that published by Valdez-Flores et al. (2010), who make full use of the available data from both the NIOSH and UCC cohorts. The effect was modeled as a standard Cox proportional log-linear hazards model (i.e., exponentiated linear) function of cumulative EO exposure (ppm-days) treated as a continuous variable.

The EO IRIS Assessment focuses the cancer risk assessment on lymphoid tumors (defined by NIOSH as including non-Hodgkin's lymphoma, lymphocytic leukemia and multiple myeloma) and breast cancer incidence. The weight of evidence does not support breast cancer as an endpoint for risk assessment (see Appendix 2). Therefore, our analysis focuses on the mortality data for lymphohematopoietic (LH) tissue cancers including leukemia (and specific myeloid and lymphocytic leukemia), non Hodgkin's lymphoma (NHL), multiple myeloma (MM) and "lymphoid" cancers (a grouping developed in Steenland et al. (2004) that included NHL, MM, and lymphocytic leukemia).

Valdez-Flores et al. (2010) propose a range of 1-3 ppb based on the Maximum Likelihood Estimate (MLE) of the Effective Concentrations (ECs) associated with an extra risk of one-in-a-million [EC(1/million)] (see Table 2).<sup>60</sup> The authors select the MLE as the most reliable data for point of departure because the Lowest Effective Concentrations (LECs), the 95% lower bound on the ECs, are insensitive to the magnitude of the best estimated slope, which can be negative, yet have a positive 95% upper confidence limit resulting in a finite LEC as occurred for multiple myeloma.

Table 2: Maximum Likelihood Estimate (MLE) of the EC (1/million) and Lowest Effective Concentration (LEC)

EO type of cancer (mortality)	MLE UCC & NIOSH (ppb)	LEC UCC & NIOSH (ppb)	LEC NIOSH only (ppb)
Lymphoid	1.5	0.5	0.2
Non-Hodgkin's lymphoma	2.3	0.9	0.8
Multiple Myeloma	Negative slope, value not calculated	1.2	0.8
Leukemia	9.2	0.9	0.9
Lymphocytic Leukemia	2.4	0.9	0.9
Breast cancer	0.7	0.1	0.1

<sup>60</sup> NIOSH only provided ACC with the breast cancer mortality and not the incidence data, despite multiple requests for the incidence data. The results from the breast cancer mortality are included in Table 2 for completeness.

EO type of cancer (mortality)	MLE UCC & NIOSH (ppb)	LEC UCC & NIOSH (ppb)	LEC NIOSH only (ppb)
Range for LHC	1.5-9.2	0.5-1.2	0.4-0.9
Range for LHC and breast cancer	0.7-9.2	0.1-1.2	0.1-0.9

The MLE and LEC values reported in Table 2 are conservative values because (a) extra risk was calculated despite no statistically significant slope in the exposure-response analyses; (b) the NIOSH data was included without adjustment for likelihood of underestimation of exposures; and (c) the limited evidence of cancer risk based on the entire body of epidemiologic evidence (summarized in Appendix 2).

The EO IRIS Assessment and Valdez-Flores et al. (2010) identify several differences between the two approaches in deriving their recommended 1/million exposure levels to use as points of departure (see Table 3).<sup>61</sup>

Table 3: Approximate sources of differences between Valdez-Flores et al. (2010) and EO IRIS Assessment approaches

Valdez-Flores et al (2010) compared to EO IRIS Assessment	Reference	Factor
Extra risk at age 70 instead of 85 years	Valdez-Flores et al. (2010), p. 319	2.3
Different approaches to implementing age-adjusted adjustment factor (ADAF)	Valdez-Flores et al. (2010), p. 319 used an approach that adjusted the slope; EPA's cancer risk assessment guidelines (2005) use 1.66	1.66
Use of incidence background rates compared to mortality background rates in lymphoid tumor unit risk estimation (incidence/mortality ratio, $R_{i/m}$ ).	$R_{i/m} = 5.26/1.99$ The EO IRIS Assessment unit risk using background lymphoid cancer incidence rates with model for lymphoid mortality data = 5.26/ppm, and unit risk using background	2.64

<sup>61</sup> See EO IRIS Assessment, Appendix A, at A-33 – A-35.

	mortality rates with model for lymphoid mortality data is 1.99/ppm; see Table 4-7, page 4-23; whereas Valdez-Flores et al. (2010) unit risk using background lymphoid mortality rates with model for lymphoid mortality data	
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Valdez-Flores et al (2010) used well-accepted statistical principles to guide decisions about whether to include a lag period, how to calculate the degrees of freedom, and whether the MLE for the EC (1/million) can be interpolated within the lower region of the experimental data set. For example, because there was no significance between the models with and without a lag period and no clear biological plausibility for selection of a specific lag period, the more parsimonious model (no lag) was selected. In contrast, the IRIS Program tested different lag periods and knots but did not fully account for the higher degrees of freedom typically considered when different ranges of values are tested.

Valdez-Flores et al. (2010) also modeled down to  $10^{-6}$  risk, whereas the IRIS Program modeled to  $10^{-2}$  risk and used the LEC01 as a point of departure (POD) for linear low-dose extrapolation. Valdez-Flores et al. (2010) suggest that PODs should be within the range of observed exposures, and chose a  $10^{-6}$  risk level because the corresponding exposure level was in the range of the observed occupational exposures (converted to equivalent environmental exposures). Thus, Valdez-Flores et al. (2010) fully used the experimental data to derive a  $10^{-6}$  risk level.

An additional difference that is not captured in Table 3 is the EO IRIS Assessment estimates risk for both lymphoid and breast cancer, whereas Valdez-Flores et al. (2010) estimates risk for lymphoid tumors alone. As discussed above and in greater detail in Appendix 2, breast cancer is not a target of EO. The EO IRIS Assessment recognizes that magnitudes of increased risks for breast cancer were not large and implies that the evidence is weaker than that for lymphoid tumors. Despite these issues, the EO IRIS Assessment introduces breast cancer as a target organ and inappropriately develops a risk value. Uncertainties described by Steenland et al. (2003) related to the breast cancer incidence study are dismissed as unimportant. It is notable that the ratio between risk for lymphoid plus breast cancer incidence (6.06 per ppm)<sup>62</sup> divided by the risk for lymphoid tumor incidence alone (5.26 per ppm)<sup>63</sup> is only 1.15.

<sup>62</sup> EO IRIS Assessment, at 4-58.

<sup>63</sup> *Id.* at 4-31.

As discussed above, the NIOSH exposure assessment was not validated prior to the late 1970s and likely underestimated exposures. In contrast, the UCC exposure estimation from the 1940s to 1970s was based on actual data from similar operations during the same time period.<sup>64</sup> The greatest uncertainty is between 1925-1939, but only 4.8% of the UCC cohort had work history before 1940.<sup>65</sup> These uncertainties are no greater than the NIOSH study uncertainties and do not justify study rejection for exposure-response analysis. Both studies are well-conducted epidemiology studies with comparable power in terms of number of events for males and of comparable utility in terms of individual exposure estimates. In fact, the UCC study was originally a NIOSH study, in that it was nested within a NIOSH/UCC collaborative study of 29,000 UCC workers in the Kanawha Valley of West Virginia.<sup>66</sup>

The EO IRIS Assessment also criticizes Valdez-Flores et al. (2010) for not using any log cumulative exposure models which were found to be statistically significant in analyses by Steenland et al. (2004), consistent with the apparent supralinearity of the NIOSH exposure-response data. Yet, the EO IRIS Assessment also considers the log cumulative exposure model to be “problematic because this model, which is intended to fit the full range of occupational exposures in the study, is inherently supralinear ..., with the slope approaching infinity as exposures decrease towards zero, and results can be unstable for low exposures.”<sup>67</sup>

Similarly, the IRIS Program rejected other statistically significant models due to unstable results for low exposures. As noted above, the assumption of supralinearity is based on a flawed statistical analysis of its preferred-model fit and on a misleading visual comparison of invalidly overlaid models plotted in relation to categorical data grouped in quartiles instead of considering the pattern of RR for individual cases, which more realistically reveals a very noisy data cloud through which the simpler and traditionally accepted Cox proportional model fits as well as the supralinear spline model.

Crump (2005) noted that:

Because of these potential distortions of the exposure-response shape, one should be cautious in drawing conclusions about the shape of the exposure response from epidemiological data. Since even random, unbiased errors in exposure measurement will convert a linear exposure response, and can convert sub-linear

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<sup>64</sup> Swaen et al. (2009).

<sup>65</sup> *Id.*

<sup>66</sup> Rinsky RA, Ott G, Ward E, Greenberg H, Halperin W, Leet T. 1988. Study of mortality among chemical workers in the Kanawha Valley of West Virginia. *Am J Ind Med*, 13: 429-38.

<sup>67</sup> EO IRIS Assessment, at 4-10.

response, into a seemingly supralinear shape, one should be particular[ly] cautious about concluding an exposure-response is truly supralinear. In particular, it could be inadvisable to extrapolate an observed supralinear exposure response to low exposures to predict human risk.<sup>68</sup>

Crump's caution is especially relevant to the NIOSH data in light of the high potential for exposure misclassification in the earlier years of the NIOSH study when there was no data to validate the NIOSH exposure model, as described above. EPA's cancer risk assessment guidelines echo this caution: "a steep slope [i.e., supralinear] also indicates that errors in an exposure assessment can lead to large errors in estimating risk."<sup>69</sup>

#### **D. Conclusion**

The 2014 NATA fails to meet the requirements of the IQA and the OMB and EPA Guidelines because its use of the EO IRIS Assessment is not the best available science. Therefore, the 2014 NATA risk estimates for EO should be withdrawn and corrected to reflect scientifically-supportable risk values and EPA should not use the EO IRIS Assessment's inhalation RSC of 0.1 ppt to calculate EO risk in its ongoing CAA Section 112 RTR rulemakings and other regulatory actions. As discussed above, a more reasonable and scientifically supportable approach to an exposure response analysis yields ranges for the MLE (1.5-9.2 ppb) and LEC (0.5-1.2 ppb) that are more than three orders of magnitude greater than the EO IRIS Assessment's environmental concentration associated with one-in-a-million risk.

Sincerely,

*William Gullledge*

William P. Gullledge  
Senior Director  
Chemical Products & Technology Division

Enclosures:

Appendix 1 – Statistical Issues with EPA's Calculation of p-values and AIC's for Spline Models and Linear Models in the EO IRIS 2016

Appendix 2 – Brief Summary of Epidemiological Data for EO

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<sup>68</sup> Crump KS. 2005. The effect of random error in exposure measurement upon the shape of the exposure response. Dose-Response, 3: 456-64.

<sup>69</sup> EPA, Guidelines for Carcinogen Risk Assessment, at 3-19.



**Statistical Issues with EPA's Calculation of p-values and AIC's for Spline Models and Linear Models in the EO IRIS 2016**

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**Introduction**

The document "Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75-21-8) In Support of Summary Information on the Integrated Risk Information System (IRIS), December 2016" (EO IRIS 2016) has several statistical inaccuracies that play an important role in model selection and, ultimately, in the risk assessment of EtO. The exposure-response modeling of lymphoid mortality for the NIOSH study is reviewed here, and statistical pitfalls are highlighted. EPA's statistical numbers are corrected herein and new results are derived. These corrected results question conclusions drawn by EPA about model selection. Although EPA's conclusions for the other endpoints are not analyzed herein, similar statistical pitfalls must have been incurred, as the statistical pitfalls are related to the methodology that was used for all endpoints analyzed by EPA.

Table 1 reproduces Table 4-6 of EO IRIS 2016. In this table EPA summarizes how the linear spline model with knot at 1600 ppm × days was selected to describe the relationship between lymphoid mortality rate ratio and cumulative exposures to EO. The summary in the table indicates that the model was selected because: a) adequate statistical fit; b) adequate visual fit; c) including local fit (visual) to low-exposure range; linear fit; and d) AIC within two units of lowest AIC models considered.

It can also be shown (using the likelihood ratio test -- analyses not presented here) that EPA's selected linear spline model does not fit the NIOSH lymphoid mortality data statistically significantly better (at the 5% significance level) than the nested linear model. Similarly, log-linear spline model with knot at 1600 ppm-days does not fit the NIOSH lymphoid mortality data statistically significantly better (at the 5% significance level) than the nested log-linear model. Thus, according to the following SAB recommendation on page 12, the log-linear and the linear models should be preferred over the log-linear spline and linear spline models, respectively:

Third, the principle of parsimony (the desire to explain phenomena using fewer parameters) should be considered. Attention to this principle becomes even more important as the information in the analysis dataset becomes even more limited.

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Thus, models with very few estimated parameters should be favored in cases where there are only a few events in the dataset.

Table 1. The following table has been extracted from EO IRIS 2016 Table 4-6

<b>Table 4–6. Models considered for modeling the exposure-response data for lymphoid cancer mortality in both sexes in the National Institute for Occupational Safety and Health cohort for the derivation of unit risk estimates</b>			
<b>Model<sup>a</sup></b>	<b><i>p</i>-value<sup>b</sup></b>	<b>AIC<sup>c</sup></b>	<b>Comments</b>
<b>Two-piece spline models</b>			
Linear spline model with knot at 1,600 ppm × days	0.07	462.1	<b>SELECTED.</b> Adequate statistical and visual fit, including local fit to low-exposure range; linear model; AIC within two units of lowest AIC of models considered.
Linear spline model with knot at 100 ppm × days	0.046	461.4	Good overall statistical fit and lowest AIC of two-piece spline models, but poor local fit to the low-exposure region, with no cases below the knot.
Log-linear spline model with knot at 1,600 ppm × days	0.07	462.6	Linear model preferred to log-linear (see text above).
Log-linear spline model with knot at 100 ppm × days	0.047	461.8	Good overall statistical fit and tied for lowest AIC <sup>c</sup> of two-piece spline models, but poor local fit to the low-exposure region, with no cases below the knot.
<b>Linear (ERR) models (<math>RR = 1 + \beta \times \text{exposure}</math>)</b>			
Linear model	0.13	463.2	Not statistically significant overall fit and poor visual fit.
Linear model with log cumulative exposure	0.02	460.2	Good overall statistical fit, but poor local fit to the low-exposure region.
Linear model with square-root transformation of cumulative exposure	0.053	461.8	Borderline statistical fit, but poor local fit to the low-exposure region.
<b>Log-linear (Cox regression) models (<math>RR = e^{\beta \times \text{exposure}}</math>)</b>			
Log-linear model (standard Cox regression model)	0.22	464.4	Not statistically significant overall fit and poor visual fit.
Log-linear model with log cumulative exposure	0.02	460.4	Good overall statistical fit; lowest AIC <sup>c</sup> of models considered; low-exposure slope becomes increasingly steep as exposures decrease, and large unit risk estimates can result; preference given to the two-piece spline models because they have a better ability to provide a good local fit to the low-exposure range.
Log-linear model with square-root transformation of cumulative exposure	0.08	462.8	Not statistically significant overall fit and poor visual fit.

<sup>a</sup>All with cumulative exposure as the exposure variable, except where noted, and with a 15-yr lag.

<sup>b</sup>*p*-values from likelihood ratio test, except for linear regression of categorical results, where Wald *p*-values are reported. *p* < 0.05 considered “good” statistical fit; 0.05 < *p* < 0.10 considered “adequate” statistical fit if significant exposure-response relationships have already been established with similar models.

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<sup>c</sup>AICs for linear models are directly comparable and AICs for log-linear models are directly comparable. However, for the lymphoid cancer data, SAS proc NLP consistently yielded -2LLs and AICs about 0.4 units lower than proc PHREG for the same models, including the null model, presumably for computational processing reasons, and proc NLP was used for the linear RR models. Thus, AICs for linear models are equivalent to AICs about 0.4 units higher for log-linear models. No AIC was calculated for the linear regression of categorical results.

### **EPA's Misinterpretation of SAB Comments about the Knot of Spline Models**

EPA justifies the p-values and AIC values for the linear spline and log-linear spline models in their Table 4-6 misquoting SAB's comments. In section D.3.2 of the appendices (reference), EPA states (emphasis added) "Table D-27 also presents the AIC values for the same models to facilitate comparison with the two-piece spline models, which include an extra parameter. [The knot is preselected and is not considered a parameter in these analyses, consistent with the SAB's concept of parsimony (SAB, 2015)].<sup>14</sup>" Their footnote 14 in the same sections states "<sup>14</sup> in some settings the principle of parsimony may suggest that the most informative analysis will rely upon fixing some parameters rather than estimating them from the data. The impact of the fixed parameter choices can be evaluated in sensitivity analyses. In the draft assessment, fixing the knot when estimating linear spline model fits from relative risk regressions is one such example" [page 12 of SAB (2015)]."

Although the SAB quote is accurate, the quote just a fragment of a response and is taken out of context. The full question and SAB response are as follows (emphasis added):

*2b: For the (low-exposure) unit risk estimates, EPA presents an estimate from the preferred model as well as a range of estimates from models considered "reasonable" for that purpose (Sections 4.1.2.3 and 4.5 and Chapter 1). Please comment on whether the rationale provided for defining the "reasonable models" is clearly and transparently described and scientifically appropriate.*

The SAB understands that the EPA considered four "reasonable" models for providing unit risk estimates; these all have unit risk estimates reported in Table 4-13. A few additional models are described in Tables 4-12 and 4-13, some of which could also be considered reasonable. The presentation of "reasonable" models considers model fit and some a priori (but not clearly articulated) notion about the acceptable shape of the dose-response function in the low-dose region. Because the data do not appear to conform to the a priori notion, the draft assessment also considers models based on an untransformed continuous exposure term or a linear regression of the categorical results as reasonable. However, these models do a poorer job reflecting the patterns in the data. Although much of the approach is scientifically appropriate, the SAB does not agree with all of the judgments. In order to strengthen the assessment and presentation, some modifications are suggested to the approach for comparing models and choosing which models are reasonable. The SAB recommends that

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the discussion be revised to provide more clarity and transparency as well as making the disposition easier to follow. In general, discussion of statistical significance should occur in a more nuanced fashion so that important perspective about the results is not lost in the tendency to turn the statistical evidence into a binary categorization of significant vs. not significant. (This can mislead readers into interpreting a pair of results as inconsistent when their p-values, effect estimates, and 95% confidence intervals are very similar, but the two p-values happen to be on opposite sides of 0.05.) Consideration of reasonable models should address the quality of fit in the region of interest for risk assessment. Prioritizing sufficiently flexible exposure parameterizations (e.g., not linear) and exposure functions with more local behavior (e.g., splines, linear and cubic) reduces the impact of highly exposed individuals on the risk estimates for lower exposures. Discarding a model because the fitted curve is “too steep” needs scientific justification. Furthermore, follow-up by the EPA is needed to clearly articulate the criteria for determining that models are reasonable as well as providing transparent definitions for frequently used terms such as “too steep,” “unstable,” “problematic,” and “credible” (p. 4-38). The SAB recommends assigning weight to certain types of models based on a modified combination of biologic plausibility and statistical considerations, and using somewhat different considerations for comparing AICs than those currently employed in the draft assessment.

Regarding statistical considerations about various models, the SAB recommends a different set of emphases in the priorities for the most reasonable models and gives guidance on the preference for their ordering. First, priority should be given to regression models that directly use individual-level exposure data. Because the NIOSH cohort has rich individual-level exposure data, linear regression of the categorical results should be de-emphasized in favor of models that directly fit individual-level exposure data. Second, among models fit to individual-level exposure data, models that are more tuned to local behavior in the data should be relied on more heavily. Thus, spline models should be given higher priority over transformations of the exposure. Third, the principle of parsimony (the desire to explain phenomena using fewer parameters) should be considered. Attention to this principle becomes even more important as the information in the analysis dataset becomes even more limited. Thus, models with very few estimated parameters should be favored in cases where there are only a few events in the dataset. To elaborate further, in some settings the principle of parsimony may suggest that the most informative analysis will rely upon fixing some parameters rather than estimating them from the data. The impact of the fixed parameter choices can be evaluated in sensitivity analyses. In the draft assessment, fixing the knot when estimating linear spline model fits from relative risk regressions is one

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such example. Use of AIC can assist with adhering to this principle of parsimony, but its application cannot be used naïvely and without also including scientific considerations. (See further discussion below.) Beyond these recommendations for choosing among models, one advantage of fitting and examining a wide range of models is to get a better understanding of the behavior of the data in the exposure regions of interest. For instance, the models shown in Table 4-13 and Figures 4-5 and 4-6 can be compared, ideally with one or more of these presentations augmented with a few more model fits, including the square root transformation of cumulative exposure, linear regression of categorical results given more categories, and several additional 2-piece linear spline models with different knots. From the comparisons, it is clear that these data suggest a general pattern of the risk rising very rapidly for low-dose exposures and then continuing to rise much more slowly for higher exposures. It is reassuring to observe that many of the fitted models reflect this pattern even though they have different sensitivity to local data.

Results of statistical analyses do not always conform to an a priori understanding of biologic plausibility. When this is the case, investigators need to reassess whether the data are correct, a different approach to model fitting should be employed, or whether the prevailing notion of biologic plausibility should be re-examined. When sufficient exploration of the fitted models has been conducted and a range of models with different properties all suggest a dose-response relationship that would not have been predicted in advance (as is the case in these NIOSH data analyses), then the remaining two considerations should be reviewed. The response to Charge Question 4 further discusses uncertainty in the exposure data. The SAB also encourages finding opportunities to use other evidence from the literature to support the observed dose-response relationship. Specifically, the SAB encourages a discussion of the Swedish sterilization workers study results using the internal comparison group.

The application of AIC for selecting models is acceptable within some constraints as outlined in the following discussion. Burnham and Anderson (2004) is an additional reference that discusses the use of AIC for model selection. (The following discussion is intended to be fairly comprehensive and thus covers points that the SAB did not identify as problematic in the draft assessment.) AIC is an appropriate tool to use for model selection for both nested and non-nested models, provided these models use the same likelihood formulation and the same data. AIC is not the preferred way to characterize model fit. For model selection, (1) AIC is not an appropriate tool for comparing across different models that are fit using different measures, such as comparing a Poisson vs. least squares fit to count data; (2) one should not use AICs to compare models using different

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transformations of the outcome variable; and (3) comparing AICs from models estimated using different software tools, including different implementations within the same statistical package can be challenging because many calculations of AIC remove constants in the likelihood from the estimated AIC. These AIC features require that users interested in comparing AICs across different software routines (even those within one statistical package) understand exactly what likelihood is being maximized and how the AIC is calculated. AIC can be used to compare the same regression model with the same outcome variable and different predictors whether or not these models are nested. This gives a consistent estimate of the mean-squared prediction error (MSPE), which is one criterion for choosing a model. Finally, the theory behind this MSPE criterion can break down with a large number of models. Thus, naïve applications of AIC for model selection can be problematic (but are not necessarily so in any particular application). In particular, differences in AICs could be an artifact of how the calculation was done. This is a possible difference between the linear and exponential relative risk models applied to the breast cancer incidence data. Although the EPA provided some clarification about its approach in its February 19, 2015 memo to the SAB, the SAB still does not have sufficient information to determine whether or not this is the case.

In conclusion, although the SAB concurs with the EPA's selected model, it believes that aspects of EPA's approach to model selection can be refined and that more transparency in the presentation is needed.

### Summary of recommendations:

- Revise the discussion to provide more clarity and transparency as well as making the disposition easier to follow.
- Discarding a model because the fitted curve is "too steep" is only acceptable when there is scientific justification.
- Clearly articulate the criteria for determining that models are reasonable as well as providing transparent definitions for frequently used terms such as "too steep," "unstable," "problematic," and "credible".
- Assign weight to various models based on a modified combination of biological plausibility and statistical considerations; use somewhat different considerations for comparing AICs than those currently employed in the draft assessment.
- Use a different set of emphases in the priorities for the most reasonable models; detailed suggestions are provided by the SAB in this response.

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*2c: For analyses using a two-piece spline model, please comment on whether the method used to identify knots (Section 4.1.2.3 and Appendix D) is transparently described and scientifically appropriate.*

The method used to identify the knots involves a sequential search over a range of plausible knots to identify the value at which the likelihood is maximized. This is scientifically appropriate and a practical solution that is transparently described.

The quote from EPA states “[The knot is preselected and is not considered a parameter in these analyses, consistent with the SAB’s concept of parsimony (SAB, 2015)].” However, EPA also states on footnote a to Table D-27 “knots were obtained by doing a grid search by increments of 100 ppm x days and then interpolating where appropriate” and foot note b states “For models with very low knots, alternate knots were obtained from local maximum likelihoods because of the small number of cases informing the slope of the low-exposure spline for low knots (see Figure D-14).” EPA further states on page D-41 (emphasis added) “For the two-piece log-linear model, the single knot was chosen at 100 ppm-days based on a comparison of likelihoods assessed every 100 ppm-day from 100 to 15,000. The best likelihood was at 100 ppm-days. Figure D-15 below shows the likelihood versus the knots. Figure D-15 also suggests a local maximum likelihood near 1,600 ppm-days.”

In summary, EPA’s description of how the knots for the linear spline and log-linear spline models were found clearly indicate that the knots were not fixed parameters, but rather were optimized numerically and in this way were estimated from the data that were fit. That is, the knots used by EPA for the linear and log-linear spline models were determined using the NIOSH data, so that the knot maximized the likelihood of the spline model. The knots, therefore, were not fixed parameters independent of the NIOSH data, as would be the case in SAB discussion of an example. EPA contradicts itself when it states “[The knot is preselected and is not considered a parameter in these analyses, consistent with the SAB’s concept of parsimony (SAB, 2015)].<sup>14</sup>” The latter EPA statement is simply false, because each knot value derived by EPA was in fact optimized (i.e., estimated) by EPA to best fit a corresponding model to a specific set of data. This fact has no relevance at all to the concept of parsimony in model selection, which refers to preference for selecting among different models the one(s) that has (have) the fewest total number ( $k$ ) of estimated parameters. The parsimony concept is also expressed in the definition of the Akaike Information Criterion (AIC), which is proportional to the value of  $k$ , insofar as superior models are identified as those with smaller associated values of AIC. Likewise, a p-value for goodness of model fit is typically evaluated in relation to a corresponding value of the total number of degrees of freedom (DF) associated with that fit, and the latter number is always defined as the total number ( $n$ ) of data points modeled minus the total number ( $k$ ) of estimated model parameters, i.e.,  $DF = n - k$ . An invalid reduction in  $k$  (e.g., by improperly considering a parameter “fixed” when in fact it was estimated to get a best fit for that model), therefore always improperly inflates the value of DF, which results in an erroneously high p-value for goodness-

of-fit that falsely magnifies the likelihood that deviations between data and a model fit to those data are due only to chance (i.e., due only to sampling error).

### **Misinterpretation of Degrees of Freedom Results in Miscalculated p-values, AIC and Incorrect Model Selection**

The “log-linear spline model with knot at 1,600 ppm-days” has three parameters that each were estimated: slope below the knot, slope above the knot, and the knot itself. However, when EPA calculated a corresponding p-value associated with its reported chi-square test for improved fit relative to an associated null model, EPA used only two degrees of freedom for this calculation. This resulted in artificially and erroneously inflating the measure of improved fit used to compare the linear spline model to other models for which p-values were calculated using degrees of freedom that accurately reflected the total number of estimated parameters associated with other model fits being compared. Specifically, EPA did not include the degree of freedom associated with the separate procedure EPA applied to numerically and graphically maximize the log likelihood of each linear spline model for which an optimum knot value was also estimated. By failing to account for the degree of freedom associated with knot-estimation, the p-value EPA reported for each such linear spline model was miscalculated to yield a lower p-value (indicating an unrealistically improved fit) than would be produced had the correct number of degrees of freedom been used by EPA for each such calculation.

In using the approach EPA took in this regard, EPA may have misinterpreted comments of the EPA (2015) Science Advisory Board (SAB) review of the EPA (2014) draft IRIS document, which on pages 12–14 state that:

the principle of parsimony (the desire to explain phenomena using fewer parameters) should be considered. Attention to this principle becomes even more important as the information in the analysis dataset becomes even more limited. Thus, models with very few estimated parameters should be favored in cases where there are only a few events in the dataset. To elaborate further, in some settings the principle of parsimony may suggest that the most informative analysis will rely upon fixing some parameters rather than estimating them from the data. The impact of the fixed parameter choices can be evaluated in sensitivity analyses. In the draft assessment, **fixing the knot when estimating linear spline model fits from relative risk regressions is one such example**. ... differences in AICs could be an artifact of how the calculation was done.

Importantly (as shown above), although the SAB indicated that fixing a knot value can be done as part of a practical approach to knot-value estimation, it also stated that “differences in AICs could be an artifact of how the calculation was done.” The SAB unfortunately failed to emphasize (but must be assumed to agree with the fact) that **differences in p-values from chi-square tests of improved fit relative to the null model can also reflect non-meaningful**

**artifacts** if associated p-value calculations are not done correctly. Specifically, it is not meaningful to compare (as EPA did) a p-value from a Cox linear-regression model of Log(RR) on ppm-days of exposure (defined to be associated with one degrees of freedom for each of the estimated slope of the line) to a p-value from EPA's linear spline model fit (assumed to be associated with only two degrees of freedom corresponding to its two estimated slopes) conditional on a knot value that EPA estimated by minimizing log likelihood in relation to the knot value. EPA incorrectly assumed its optimized knot-value estimate is not associated with one additional degree of freedom. Thus, EPA erroneously deflated the total degrees of freedom associated with their three-parameter linear model by evaluating it as if it had only two degrees of freedom (parameters) associated with it. Consequently, EPA miscalculated the p-value for its spline model resulting in an erroneously low p-values of ~0.07 (see Table 2), when (as explained in more detail in the next section) the correctly calculated p-value is ~2-fold greater (i.e., 0.14 to 0.15) and do not differ meaningfully from p-values associated with the more parsimonious linear Cox regression model (see corrected Table 4-6 discussed in the next section).

Table 2. SAS results given for this model in Table D-33 in Appendix D of EO IRIS 2016

Table D-33. Results of two-piece log-linear spline model for lymphoid cancer mortality, men and women combined, knot at 1,600 ppm-days						
Model fit statistics						
Criterion	Without covariates	With covariates				
-2 LOG L	463.912	458.640				
AIC	463.912	462.640				
SBC	463.912	466.581				
Testing global null hypothesis: BETA = 0						
Criterion	Without covariates	With covariates				
Likelihood ratio	5.2722	2	0.0716			
Score	5.2666	2	0.0718			
Wald	5.1436	2	0.0764			
Analysis of maximum likelihood estimates						
Parameter	DF	Parameter estimate	Standard error	$\chi^2$	Pr > ChiSq	Hazard ratio
LIN_0	1	0.0004893	0.0002554	3.6713	0.0554	1.000
LIN_1	1	0.0004864	0.0002563	3.6014	0.0577	1.000

### Miscalculated p-values: Example using the log-linear spline model with knot at 1,600 ppm-days”

The likelihood ratio test is used to test whether a fitted model significantly improves the fit of the data by estimating parameters instead of just assuming a baseline (null) model for the data. The likelihood ratio test is evaluated by comparing the likelihood of the model with the estimated parameters and the likelihood of the null model. If the likelihood of the model with the estimated parameters is equal to the likelihood of the null model, then the natural logarithm of the ratio of

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these likelihoods multiplied by two follow a Chi-Square distribution with as many degrees of freedom as the number of parameters estimated for the fitted model. Thus, if the fit of the baseline (null) model and the model with estimated parameters are not different,

$$Chi - Square(k) = \chi_k^2 = -2 \ln \left( \frac{\text{likelihood for null model}}{\text{likelihood for fitted model}} \right)$$

This can also be written as follows,

$$\chi_k^2 = -2\text{LogL}(\text{null model}) - 2\text{LogL}(\text{fitted model})$$

Here  $k$  is the number of degrees of freedom ( $k$  is the number of parameters that were estimated in excess of the parameters estimated for the null model).

For the model in Table 2 (Table D-33 in EO IRIS 2016) the  $\chi_k^2$  value was equal to 5.2722 and  $k$  was set to 2. This resulted in a p-value of 0.0716. That is, the fitted model was assumed to have two parameters; namely, the slope below the knot and the slope above the knot. The results in Table 2 are from a SAS output for the model specified. The model specified included a knot. This knot was determined so that the likelihood of the spline model was maximized. That is, the knot is another parameter that was searched for outside SAS. Because the estimation of the “knot” was done outside SAS, the SAS program did not count the knot as a parameter and, consequently, the Chi-Square test SAS reported does not reflect the fact that the knot was also estimated. The correct Chi-Square that accounts for the fact that the knot was estimated outside SAS should then be 5.2722, but  $k$  (the degrees of freedom) should be 3. This corrected calculation would result in a p-value of 0.1529. That is, the corrected p-value indicates that the likelihood of the “log-linear spline model with knot at 1,600 ppm × days” is not different from the likelihood of the null model. In plain words, there is not enough evidence indicating that the fitted log-linear spline model explains the variability in the data any better than the null model.

### **Miscalculated AICs: Example using the log-linear spline model with knot at 1,600 ppm-days**

The Akaike Information Criterion (AIC) is equal to  $2k - 2\text{LogL}$  where  $k$  is the number of parameters estimated for the model and LogL is the logarithm of the likelihood. Here, Table 2 (Table D-33 in EO IRIS 2016) lists the  $-2\text{LogL}$  as 458.640 and the AIC as 462.640. That is;

$$462.640 = 2k + 458.640$$

*The AIC and  $-2\text{LogL}$  implies that  $k$  equals 2. That is, the spline model was assumed to have estimated two parameters; namely, the slope below the knot and the slope above the knot. The results in the Table 2 consist of SAS output for the spline model specified. The model specified included a knot. This knot was pre-assigned (i.e., previously estimated using a separate optimization procedure outside the SAS run), so the likelihood of the model was maximized only*

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*conditional on* the estimated knot-value used for that calculation. Consequently, the knot must be treated as an additional parameter that was estimated outside SAS. Because the estimation of the “knot” was done outside SAS, the SAS run performed by EPA did not count the knot as a model parameter and, consequently, the resulting AIC value it obtained does not reflect that the knot was in fact estimated. EPA could have requested SAS to account properly for the extra degree of freedom properly associated with its estimated knot value, but EPA evidently elected not to make this request of SAS.

The correct AIC, which accounts for the fact that the knot was estimated outside SAS, should instead be

$$\text{AIC} = 464.640 = 2 \times 3 + 458.640$$

These differences are summarized in corrected Table 3 below.

### **Model selection with correct AIC and p-values**

EPA selects the “linear spline model with knot at 1,600 ppm × days” for lymphoid for the following reasons:

**a) Adequate statistical fit.** EPA’s uses the erroneous p-value of 0.07 (Table 1) to select the model arguing that it is close to 0.05. However, the corrected p-value is 0.14 (Table 3) once the fact that the knot was also estimated is accounted for by adding one more degree of freedom to the chi-square distribution. The corrected p-value is now in the range of the p-values for the log-linear and linear models; in fact, it is larger than the p-value (0.13) for the linear model.

**b) Adequate visual fit.** EPA’s visual fit is dismissed in the footnote of Figure 4-3 of the EO IRIS 2016 report. The footnote reads “(Note that, with the exception of the categorical results and the linear regression of the categorical results, the different models have different implicitly estimated baseline risks; thus, they are not strictly comparable to each other in terms of RR values, i.e., along the y-axis. They are, however, comparable in terms of general shape.)” In addition to the visual-fit caveat listed by EPA in the IRIS report, they failed to indicate that the models are **not** fit to the five nonparametric rate ratios shown in the figure, but rather to the individual cases that includes nine cases of lag-15 EO unexposed workers and 44 cases with lag-15 EO cumulative exposure. That is, the graph shown in Figure 4-3 of the EO IRIS 2016 report does not show all the variability in the full data and visual comparisons can be misleading. Furthermore, the categorical rate ratios are not “the data”, but rather, non-parametric estimate of the rate ratios.

**c) Including local fit (visual) to low-exposure range; linear model.** When the models are plotted against the non-parametric rate ratios of the 44 exposed cases, all models seem to fit the

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non-parametric models about the same; which is consistent with the calculated p-values and AIC values.

**d) AIC within two units of lowest AIC of models considered.** EPA's uses the erroneous AIC value of 462.1 to select the model arguing that it is within two units from the lowest AIC (460.2 for the "linear model with log cumulative exposure"). However, the corrected AIC is 464.5 once the fact that the knot was also estimated is accounted for by adding one more parameter in the calculation of the AIC. The corrected AIC for the "linear spline model with knot at 1,600 ppm-days" is now larger than the AIC values for the linear model (463.6) and for the log-linear model (464.4).

Once the errors indicated above concerning calculating p-values, calculating AIC values, and associated adjustments for different calculations of likelihood values are all corrected, EPA's best model for lymphoid should be reconsidered. Using the criteria EPA EO IRIS uses to select a model, the best models for the lymphoid data are the "linear model" followed by the "log-linear model."

Table 3. The following table has been extracted from EO IRIS 2016 Table 4-6 and the p-values and AIC values have been corrected to reflect the degree of freedom for the knot in the spline models and to reflect the likelihood difference between SAS procedures used for linear and log-linear models

<b>Table 4–6. Models considered for modeling the exposure-response data for lymphoid cancer mortality in both sexes in the National Institute for Occupational Safety and Health cohort for the derivation of unit risk estimates</b>			
<b>Model<sup>a</sup></b>	<b>p-value<sup>b</sup></b>	<b>AIC<sup>c</sup></b>	<b>Comments</b>
<b>Two-piece spline models</b>			
Linear spline model with knot at 1,600 ppm × days	0.14	464.5	<b>SELECTED.</b> Adequate statistical and visual fit, including local fit to low-exposure range; linear model; AIC within two units of lowest AIC of models considered.
Linear spline model with knot at 100 ppm × days	0.11	463.8	Good overall statistical fit and lowest AIC of two-piece spline models, but poor local fit to the low-exposure region, with no cases below the knot.
Log-linear spline model with knot at 1,600 ppm × days	0.15	464.6	Linear model preferred to log-linear (see text above).
Log-linear spline model with knot at 100 ppm × days	0.11	463.8	Good overall statistical fit and tied for lowest AIC <sub>c</sub> of two-piece spline models, but poor local fit to the low-exposure region, with no cases below the knot.
<b>Linear (ERR) models (RR = 1 + β × exposure)</b>			
Linear model	0.13	463.6	Not statistically significant overall fit and poor visual fit.
Linear model with log cumulative exposure	0.02	460.6	Good overall statistical fit, but poor local fit to the low-exposure region.

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Model <sup>a</sup>	<i>p</i> -value <sup>b</sup>	AIC <sup>c</sup>	Comments
Linear model with square-root transformation of cumulative exposure	0.053	462.2	Borderline statistical fit, but poor local fit to the low-exposure region.
<b>Log-linear (Cox regression) models (<math>RR = e^{\beta \times \text{exposure}}</math>)</b>			
Log-linear model (standard Cox regression model)	0.22	464.4	Not statistically significant overall fit and poor visual fit.
Log-linear model with log cumulative exposure	0.02	460.4	Good overall statistical fit; lowest AIC <sup>c</sup> of models considered; low-exposure slope becomes increasingly steep as exposures decrease, and large unit risk estimates can result; preference given to the two-piece spline models because they have a better ability to provide a good local fit to the low-exposure range.
Log-linear model with square-root transformation of cumulative exposure	0.08	462.8	Not statistically significant overall fit and poor visual fit.

<sup>a</sup>All with cumulative exposure as the exposure variable, except where noted, and with a 15-yr lag.

<sup>b</sup>*p*-values from likelihood ratio test, except for linear regression of categorical results, where Wald *p*-values are reported. *p* < 0.05 considered “good” statistical fit; 0.05 < *p* < 0.10 considered “adequate” statistical fit if significant exposure-response relationships have already been established with similar models.

<sup>c</sup>AICs for linear models are directly comparable and AICs for log-linear models are directly comparable. However, for the lymphoid cancer data, SAS proc NLP (where NLP = nonlinear programming) consistently yielded –2LLs and AICs about 0.4 units lower than proc PHREG for the same models, including the null model, presumably for computational processing reasons, and proc NLP was used for the linear RR models. Thus, AICs for linear models are equivalent to AICs about 0.4 units higher for log-linear models. No AIC was calculated for the linear regression of categorical results.

Note: In order to make the AICs comparable for different models, the AIC’s for the linear models have been increased by 0.4 to reflect the discrepancy in the –2LogL values reported by the SAS proc NLP and by SAS PHREG (as indicated in green in this table).

Figures 1 to 4 are versions of EPA’s Figure 4-3. A model (TrueLogL – dotted light blue line in the graphs) was added to relieve the caveat posed by EPA in the footnote to Figure 4-3 about the visual comparability of fitted models. The TrueLogL model is an approximation to the correct visual representation of the log-linear (standard Proportional Hazards Model fit to the NIOSH full data set) after adjusting for the difference in baseline risks between the rate ratios and the loglinear model. In Figures 1 to 4, all the individual RR (categorical) in the light blue box of the figure are summarized by the red dot in the light blue box (EPA’s 5 RRs for the last quartile). Similarly, all the individual RR (categorical) in the light yellow box of the figure are summarized by the red dot in the light yellow box (EPA’s 5 RRs for the third quartile). In the same way, all the individual RR (categorical) in the light green box of the figure are summarized by the red dot in the light green box (EPA’s 5 RRs for the second quartile). Finally, all the individual RR (categorical) in the clear box, next to the vertical axis of the figure, are summarized by the red dot in the clear box (EPA’s 5 RRs for the first quartile).

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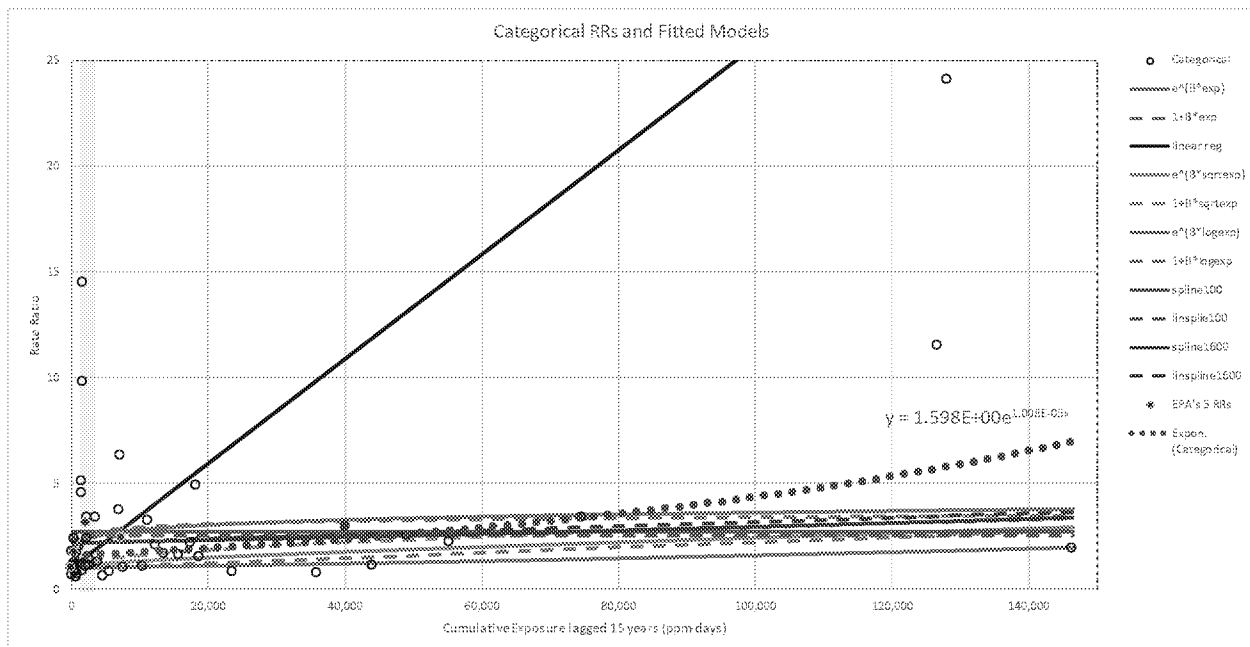
**Figure 1** shows all EPA models plotted versus the individual nonparametric rate ratios (categorical) and grouped rate ratios (EPA's 5 RRs). The range of cumulative exposures when the rate ratios for all cases are plotted is much bigger than the range of cumulative exposures when the rate ratios are averaged over several cases (EPA's 5 RRs). The variability of the rate ratios for the individual cases (categorical) is much larger than the variability of the rate ratios averaged over several cases (EPA's 5 RRs). Except for the unacceptable linear model fit to four rate ratios (linear reg), all models fit approximately the same in Figure 1. The model Expon. (Categorical) is a plot of the approximate log-linear model ( $e^{(B \cdot \text{exp})}$ ) adjusted by dividing the model for the hazard rate by the baseline hazard rate of the nonparametric estimates.

**Figure 2** shows an expansion of the low-left corner of Figure 1. These are all EPA models plotted versus the nonparametric rate ratios with values between 0 and 3.5 and cumulative exposures between 0 and 40,000 ppm-days. This graph resembles Figure 4-3 of the EO IRIS 2016 report with the exception that rate ratios based on individual cases (categorical) that are in the range of the graph are plotted in addition to the aggregated four points used by EPA (EPA's 5 RRs).

**Figure 3** is the same as Figure 1 except that the vertical scale is shown using a logarithmic scale of the rate ratios to visualize the linear difference between the fitted models and the rate ratios.

**Figure 4** is the same as Figure 2 except that the vertical scale is shown using a logarithmic scale of the rate ratios to visualize the linear difference between the fitted models and the rate ratios.

Figure 1. EPA models plotted against all lymphoid rate ratios in the NIOSH data



## Appendix 1

Figure 2. EPA models plotted against all lymphoid rate ratios in the NIOSH data in the low exposure concentration range and with the rate ratio truncated to the same range of EPA's Figure 4-3.

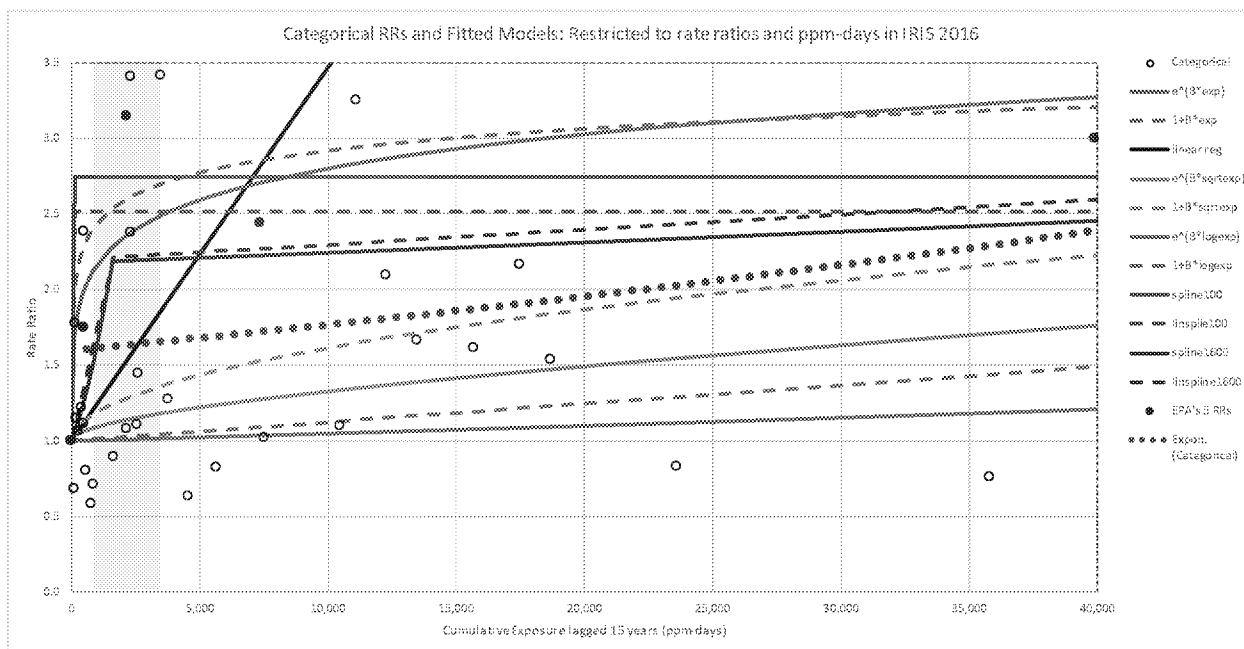
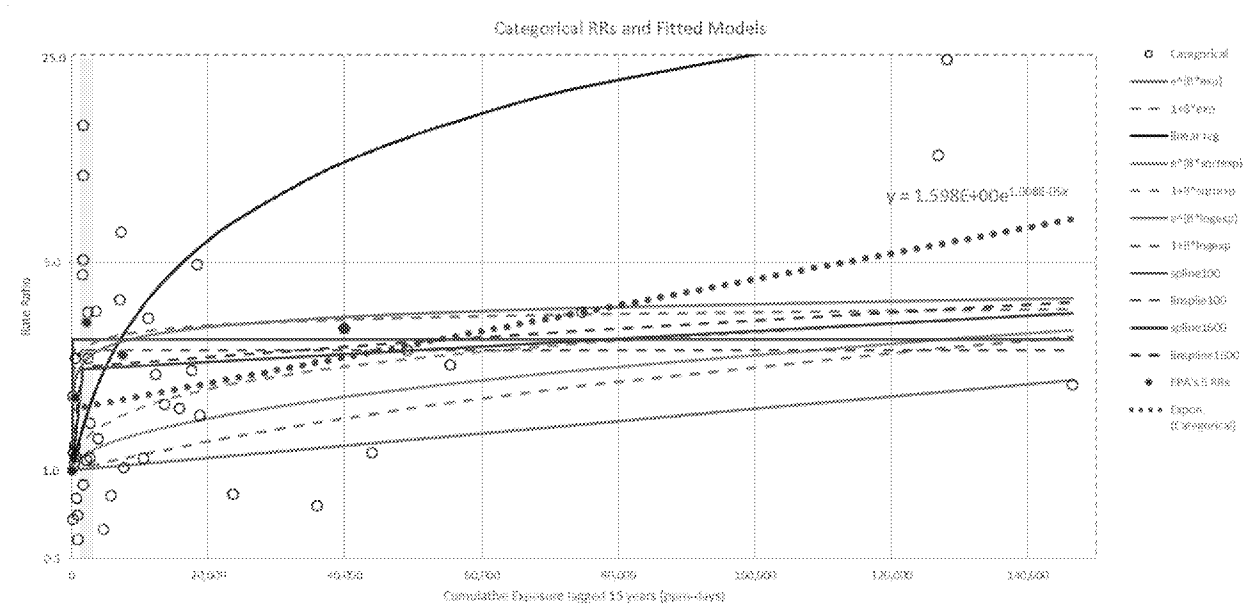
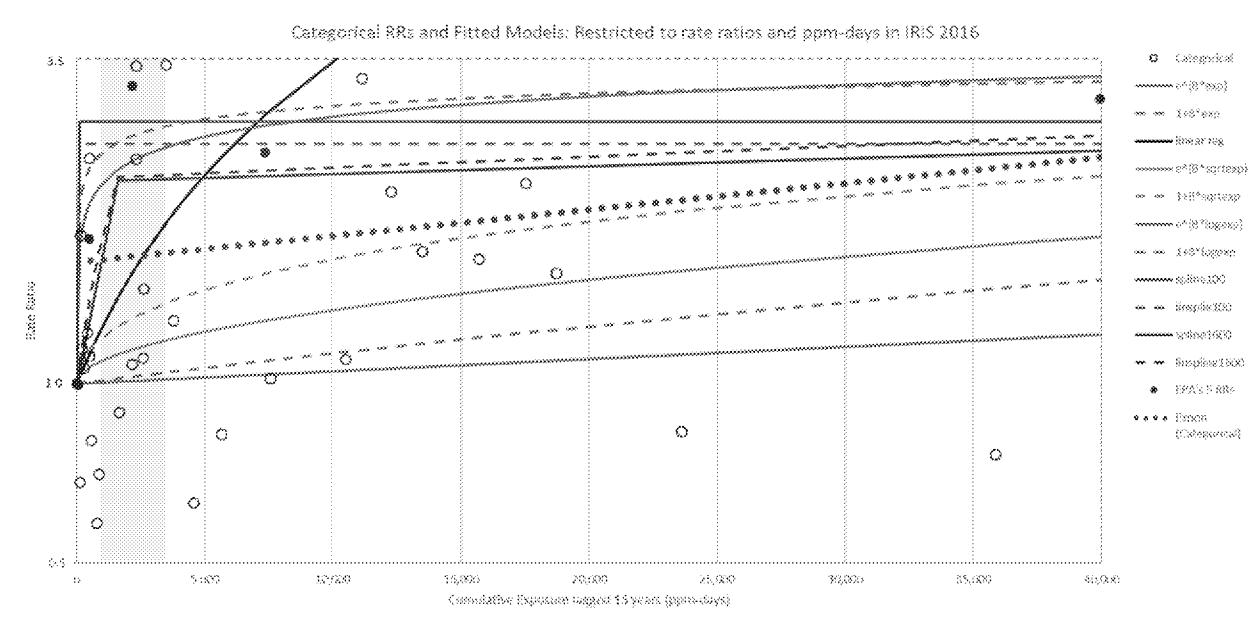


Figure 3. EPA models plotted against the logarithm of all lymphoid rate ratios in the NIOSH data



## Appendix 1

Figure 4. EPA models plotted against the logarithm all lymphoid rate ratios in the NIOSH data in the low exposure concentration range and with the rate ratio truncated to the same range of EPA's Figure 4-3.



## Appendix 2

### Brief Summary of Epidemiological Data for EO

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The relevant epidemiology, despite the large number of studies published over a forty-year period, are not supportive of a determination that EO is a human carcinogen. While interest has centered on leukemia, other blood related malignancies, and recently breast cancer: (1) there are numerous inconsistencies across the studies, (2) elevated risks above background are found in isolated studies and the effect size is of small magnitude, and (3) there is an absence of a clear exposure-response relation for any specific cancer type.

Examination of the specific cancer subtypes (leukemia, non-Hodgkin's lymphoma [NHL], Hodgkin's disease [HD], multiple myeloma [MM] and lymphohematopoietic cancers [LH] overall) illustrates the absence of clear evidence of carcinogenicity and no clear choice for a target organ should a dose-response be attempted. Table 1 summarizes the individual and overall findings from the EO studies for leukemia. Taking the ratio of the total observed cases and the total expected number of cases yields a summary risk estimate. The total number of deaths due to leukemia is 64 with 56.86 expected for an SMR /SIR of 1.13 (95% CI: 0.87-1.44). It is noteworthy that Hogstedt's increase was mainly attributable to myeloid leukemias, while Steenland focused on lymphocytic leukemia in the lymphoid category. As shown by Shore and Teta in their meta-analyses, Hogstedt is an outlier that is statistically different in findings from the other studies, i.e., a cause of heterogeneity. Furthermore, it is incorrect to include a cluster which gave rise to the hypothesis in a summary risk estimate. Excluding Hogstedt, yields 57 observed leukemias and 56.06 expected for an SMR/SIR of 1.02 (95% CI: 0.77, 1.32). Clearly Hogstedt's hypothesis of EO as a cause of leukemia has not been confirmed.

**Table 1. Leukemia in Epidemiology Studies of Ethylene Oxide**

Publication	Observed	Expected	Obs./Exp. (95% CI)
Hogstedt 1979, 1986, 1988	7	0.80	9.21* (3.70, 19.0)
Lymphocytic	2	---	---
Myeloid	3	---	---
NOS	2	---	---
Hagmar 1991/Hagmar 1995/ Mikoczy 2011	5	3.58	1.40 (0.45, 3.26)
Thiess 1981/Kiesselbach 1990	2	2.35	0.85 (0.10, 3.07)
Morgan 1981/Divine 1990	0	0.60	0.00 (0.00, 6.57)
Greenberg 1990/Teta 1993/ Swaen 2009	11	11.8	0.93 (0.47, 1.67)
Steenland 1991/Stayner 1993/ Steenland 2004	29	29.3	0.99 (0.71, 1.36)
Bisanti 1993	2	0.30	6.50 (0.79, 23.5)
Gardner 1989/Coggon 2004	5	4.60	1.08 (0.35, 2.51)
Olsen 1997	2	3.00	0.67 (0.08, 2.40)
Norman 1995	1	0.54	1.85 (0.05, 10.3)
Summary	64	56.9	1.13 (0.87, 1.44)
Summary (-Hogstedt)	57	56.1	1.02 (0.77, 1.32)

For HD there were 17 observed compared to 10.84 expected (1.57; 95% CI: 0.91-2.51) (Table 2). The Swaen case-control study was included and an expected number was derived to combine these results with those of the cohort studies. (The proportion of controls exposed, 5%, was applied to the case group of 10 cases yielding an expected exposed of 0.5). Relying only on the two strongest studies (Swaen 2009 and Steenland 2004) yields for HD, 6 vs. 6.54 (0.92; 95% CI: 0.34, 2.0). The Swaen 2009 UCC cohort had no deaths due to HD.

**Table 2. Hodgkin Disease in Epidemiology Studies of Ethylene Oxide**

Publication	Observed	Expected	Obs./Exp. (95% CI)
Hogstedt 1979, 1986, 1988	0	---	---
Hagmar 1991/Hagmar 1995/ Mikoczy 2011	1	1.31	0.76 (0.02, 4.25)
Thiess 1981/Kiesselbach 1990	---	---	---
Morgan 1981/Divine 1990	3	0.40	8.34* (1.68, 24.4)
Greenberg 1990/Teta 1993/ Swaen 2009	0	1.70	0.00* (0.00, 0.22)
Steenland 1991/Stayner 1993/ Steenland 2004	6	4.84	1.24 (0.53, 2.43)
Bisanti 1993	---	---	---
Gardner 1989/Coggon 2004	2	1.05	1.91 (0.23, 6.89)
Olsen 1997	2	0.70	2.86 (0.35, 10.3)
Norman 1995	0	0.34	0.00 (0.00, 10.9)
Swaen 1996	3	0.50	8.50* (1.40, 39.9)
Summary	17	10.8	1.57 (0.91, 2.51)

Two studies provided no data for MM (Kiesselbach 1990 and Bisanti 1993) and four others failed to provide expected values (Hogstedt 1988, Divine 1990, Olsen 1997, and Swaen 2009) (Table 3). Upon contacting Dow, we were able to obtain the expected number of 5.1 for MM. Based on the studies with complete information, there are 22 observed and 24.0 expected for a summary estimate of 0.92 (Table 3). This result is heavily weighted by the largest study, Steenland et al. 2004, who reported 13 cases vs. 14.13 expected (SMR= 0.92). This summary risk estimate does not indicate an association with MM.

**Table 3. Multiple Myeloma in Epidemiology Studies of Ethylene Oxide**

Publication	Observed	Expected	Obs./Exp. (95% CI)
Hogstedt 1979, 1986, 1988	0	---	---
Hagmar 1991/Hagmar 1995/ Mikoczy 2011	2	2.08	0.96 (0.12, 3.47)
Thiess 1981/Kiesselbach 1990	---	---	---
Morgan 1981/Divine 1990	0	---	---
Greenberg 1990/Teta 1993/ Swaen 2009	3	5.10	0.59 (0.12, 1.72)
Steenland 1991/Stayner 1993/ Steenland 2004	13	14.1	0.92 (0.49, 1.57)
Bisanti 1993	---	---	---
Gardner 1989/Coggon 2004	3	2.50	1.20 (0.25, 3.49)
Olsen 1997	1	NR	NR
Norman 1995	1	0.23	4.34 (0.11, 24.2)
Summary	22	24.0	0.92 (0.57, 1.39)

Using the same method of pooling the observed and expected values of NHL across the different studies results in a meta-SMR/SIR estimate of 1.12 based on 62 observed and 55.4 expected, a small, non-statistically significant increase (Table 4).

**Table 4. Non-Hodgkins Lymphoma in Epidemiology Studies of Ethylene Oxide**

Publication	Observed	Expected	Obs./Exp. (95% CI)
Hogstedt 1979, 1986, 1988	2	---	---
Hagmar 1991/Hagmar 1995/ Mikoczy 2011	9	6.25	1.44 (0.66, 2.73)
Thiess 1981/Kiesselbach 1990	---	---	---
Morgan 1981/Divine 1990	0	0.90	0.00 (0.00, 4.04)
Greenberg 1990/Teta 1993/ Swaen 2009	12	11.5	1.05 (0.54, 1.83)
Steenland 1991/Stayner 1993/ Steenland 2004	31	31.0	1.00 (0.72, 1.35)
Bisanti 1993	3	0.20	16.9* (3.49, 49.5)
Gardner 1989/Coggon 2004	7	4.80	1.46 (0.59, 3.02)
Olsen 1997	5	NR	NR
Norman 1995	0	0.76	0.00 (0.00, 4.85)
Summary	62	55.4	1.12 (0.86, 1.43)

Examination across the ten studies of all LH cancers yields a non-statistically significant increase based on 175 observed vs. 156.97 expected (Meta-SMR/SIR = 1.11; 95% CI: 0.96, 1.29) (Table 5). Exclusion of Hogstedt would result in a weak excess (1.07) and narrow confidence interval (95% CI: 0.91, 1.25).

**Table 5. All Lymphopoietic and Hematopoietic Cancers in Epidemiology Studies of Ethylene Oxide**

Publication	Observed	Expected	Obs./Exp. (95% CI)
Hogstedt 1979, 1986, 1988	9	2.00	4.59* (2.10, 8.70)
Hagmar 1991/Hagmar 1995/ Mikoczy 2011	18	14.4	1.25 (0.74, 1.98)
Thiess 1981/Kiesselbach 1990	5	4.99	1.00 (0.32, 2.34)
Morgan 1981/Divine 1990	3	3.00	1.01 (0.20, 2.96)
Greenberg 1990/Teta 1993/ Swaen 2009	27	30.4	0.89 (0.59, 1.29)
Steenland 1991/Stayner 1993/ Steenland 2004	79	79.0	1.00 (0.79, 1.24)
Bisanti 1993	5	0.70	7.00* (2.27, 16.4)
Gardner 1989/Coggon 2004	17	12.9	1.30 (0.77, 2.10)
Olsen 1997	10	7.70	1.29 (0.62, 2.38)
Norman 1995	2	1.88	1.06 (0.13, 3.84)
Summary	175	157.0	1.11 (0.96, 1.29)
Summary (-Hogstedt)	166	155.0	1.07 (0.91, 1.25)

As discussed above, Steenland et al. (2004) grouped three LHC cancers into the “lymphoid” category and reported some positive findings for men only. This category included lymphocytic leukemias only. The original cluster reported by Hogstedt in 1979 consisted of myeloid leukemias (Table 2). The results from the only other study to examine the lymphoid category as defined by NIOSH (UCC cohort) are inconsistent with the NIOSH results (Swaen 2009). From an internal analysis using Cox proportional hazard model, no evidence of an exposure–related response was observed by Swaen et al. using the UCC EO cohort. In fact, the females in the NIOSH study are also inconsistent with the male findings for lymphohematopoietic and “lymphoid” tumors (Steenland 2004).

Steenland et al. also examined both incidence and mortality from breast cancer for the sterilizer cohort (Steenland 2003, 2004). Among the overall results for this disease endpoint among other studies, only Norman et al. (1995) reported an increase (Table 6). Hogstedt enumerated all the cancers from his numerous cohorts and updates. No breast cancer cases were identified. Similarly, there was no excess among the hospital workers studies by Coggon et al. (2004), even among those with “continual” exposure (5 observed, 7.2 expected). The data related to breast cancer derived predominately from the NIOSH studies of sterilant workers with 102 deaths and 103 expected for an SMR of 0.99 (95% CI: 0.81-1.20) (Steenland 2004) and 319 incident cases with 367 expected for a statistically significant deficit of 0.87 (95% CI: 0.77-0.97) (Steenland 2003) due to underascertainment of cases. When examined in various exposure subgroup analyses, however, NIOSH concluded there was some evidence of an increase for breast cancer.

**Table 6. Ethylene Oxide Epidemiology Studies of Female Breast Cancer**

Study	Observed	Expected	Obs./Exp. (95% CI)
Coggon et al. 2004	11	13.1	0.84 (0.42, 1.51)
Steenland et al. 2004	102	103.0	0.99 (0.81, 1.20)
Steenland et al. 2003	319	367.0	0.87* (0.77, 0.97)
Mikoczy et al. 2011	41	50.9	0.81 (0.58, 1.09)
Norman et al. 1995	12	7.0	1.72 (0.93, 2.93)
Hogstedt et al. 1986	0	---	---
Summary (incident cases only)	372	424.9	0.88* (0.79, 0.97)
Summary (mortality cases only)	113	116.1	0.97 (0.80, 1.17)

EPA recognizes that magnitudes of increased risks for breast cancer were not large and implies that the evidence is weaker than that for lymphoid tumors. Despite these issues, EPA proceeds to introduce breast cancer as a target organ in the IRIS Assessment and inappropriately develops a risk value. Uncertainties described by Steenland et al. (2003) related to the breast cancer incidence study are dismissed as unimportant by EPA. EPA agrees with Steenland that the breast cancer incidence findings are not conclusive, due to inconsistencies in the exposure-response and an incomplete cancer ascertainment. Using these data, the slopes of EPA's attempted exposure-response analyses were non-statistically significant or biologically uninterpretable, leading them to employ novel approaches for quantitative risk assessment. The modeling challenges could be anticipated given Steenland's statement of uncertainty with respect to breast cancer, "The dip in the spline curve in the region of higher exposures suggested an inconsistent or non-monotonic risk with increasing exposure."

The Agency downplays the potential for selection bias based on the consistency in the incidence study between results from full cohort and those from the subgroup interviewed (68% of study subjects). Selection bias (referred to by Steenland as "possible biases due to patterns of non-response") remains a concern, however, with duration reported as a stronger risk factor than cumulative exposure in both analyses. Those who work longer stay in the area longer and are more likely to get picked up in the state tumor registries and be found for interview, therefore with the potential to impact the results of both analyses. Shorter duration workers with lower exposures are more likely to leave the area and not be captured in the overall analyses and less likely to be interviewed. Their diagnoses get missed, creating a possible biased positive exposure-response. Steenland recognized this limitation and admitted he was unable to fully address it and listed it as one of his uncertainties:

A second possible bias was the preferential ascertainment of breast cancer among women with stable residence in states with cancer registries; women with stable residency might be expected to have longer duration of employment in companies

## Appendix 2

under study, and hence greater cumulative exposure. Unfortunately, we did not have residential history, limiting our ability to explore this possibility.

The more recent study by Mikoczy et al. (2011) has been cited as supportive of an association with breast cancer, in spite of an overall deficit (SIR=0.81; 95% CI: 0.58-1.09) based on 41 cases observed. With 15-year latency it is 0.86, also suggesting no increase. Similar to NIOSH, however, the two higher cumulative exposure groups (of three total group) had statistically significant elevated rates of breast cancer (2.76; 95% CI: 1.20-6.33 and 3.55; 95% CI: 1.58-7.93) in an *internal* Poisson analysis, due, however, to a substantial and statistically significant deficit of breast cancer in the low dose reference group (SIR=0.52; 95% CI: 0.25-0.96). There are clearly advantages to comparing workers to workers in epidemiology studies to overcome possible biases in external comparisons to the general population. However, there may also be disadvantages to using an internal comparison group that are not recognized. One danger is selecting a referent group that has an unusual excess or deficit of the disease of interest as illustrated in this study. This illustrates the problem that can arise from internal comparisons and should not always to be preferred despite what EPA contends.

In addition to LH cancers, EPA uses breast cancer as a target endpoint. We conclude that the choice of breast cancer as a target organ for EO dose-response assessment is not justified for several reasons: (1) EPA agrees that the evidence for breast cancer is even weaker than the evidence for the lymphoid category, (2) the NIOSH findings suffer from potential selection biases, show a non-monotonic increase in risk with increasing exposure, and neither mortality nor incidence rates overall exceed background rates in the general population, and (3) the breast cancer findings from the other epidemiology studies are equivocal.

There is no obvious target organ for an EO exposure-response assessment for a quantitative risk assessment. Given the weak epidemiology evidence for carcinogenicity, the lack of consistency or a clear exposure-response, the selection of a specific target organ is problematic. Using cumulative exposure as the exposure metric and the standard proportional hazard modeling, none of the slopes for the endpoints of interest are statistically significant (Valdez-Flores, Sielken, and Teta 2010). Despite the absence of a clear exposure-response for any one of the combinations, the authors proceeded to use EPA's standard procedure for unit risk estimation and estimation of exposure associated with a one-in-a-million risk. This approach was adopted by Scientific Committee on Occupational Exposure Limits (SCOEL) for the European Union in 2012 for occupational standard setting.

### References

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## Appendix 2

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## Appendix 2

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## Mahgoub, Gaida

---

**From:** Smith, Darcie  
**Sent:** Tuesday, October 16, 2018 11:25 AM  
**To:** Jones, Rhea;Rimer, Kelly  
**Cc:** Sasser, Erika;Mozingo, Kristal  
**Subject:** RE: Ethylene Oxide Update for Bill Wehrum for 10/18/18 visit  
**Attachments:** Meeting Request\_EtO Update 101818.docx

Attached.

We'll need a larger-than-normal room. I may still be missing some folks, but I tried to get everyone I thought might be speaking.

Darcie

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
📞 919.541.2076  
✉️ [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Jones, Rhea  
**Sent:** Monday, October 15, 2018 3:55 PM  
**To:** Rimer, Kelly <Rimer.Kelly@epa.gov>; Smith, Darcie <Smith.Darcie@epa.gov>  
**Cc:** Sasser, Erika <Sasser.Erika@epa.gov>  
**Subject:** Ethylene Oxide Update for Bill Wehrum for 10/18/18 visit

Hi Kelly and Darcie,

Added to the agenda for Bill Wehrum's visit to RTP on Thursday is an EtO update. It's currently on the itinerary for 3:30-4:15. Patrick is asking for a meeting request for this purpose, and once he receives it he will add it to the calendar. Darcie, could you help by preparing the meeting request? Please advise if you think someone else should be on point for this.

Thanks!

## Mahgoub, Gaida


---

**From:** Smith, Darcie  
**Sent:** Wednesday, October 17, 2018 2:49 PM  
**To:** Koerber, Mike;Rimer, Kelly  
**Cc:** Sasser, Erika  
**Subject:** RE: Sampling and Modeling Plan - EtO - Sterigenics Willowbrook .docx  
**Attachments:** Sampling and Modeling Plan - EtO - Sterigenics Willowbrook\_rev\_dps.docx

Hi –

Here's a draft back with the risk assessment piece added. Please let me know if you want more details or have a different approach in mind.

Thanks,  
Darcie

Darcie Smith  
U.S. EPA/OAQPS/ ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Koerber, Mike  
**Sent:** Wednesday, October 17, 2018 12:45 PM  
**To:** Rimer, Kelly <[Rimer.Kelly@epa.gov](mailto:Rimer.Kelly@epa.gov)>; Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Cc:** Sasser, Erika <[Sasser.Erika@epa.gov](mailto:Sasser.Erika@epa.gov)>  
**Subject:** FW: Sampling and Modeling Plan - EtO - Sterigenics Willowbrook .docx

Sorry to dump one more thing on you, but Clint has asked for a short 1-pager at a high level about the modeling and monitoring we are proposing to do. Attached is an initial piece prepared by AQAD, which I've taken the liberty to shorten. Please add a short description of the risk assessment modeling – feel free to borrow heavily from existing write-ups. I'd like to get this back to Clint tomorrow. Thank you.

Mike

---

**From:** Wayland, Richard  
**Sent:** Wednesday, October 17, 2018 11:34 AM  
**To:** Koerber, Mike <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)>; Rimer, Kelly <[Rimer.Kelly@epa.gov](mailto:Rimer.Kelly@epa.gov)>  
**Cc:** Weinstock, Lewis <[Weinstock.Lewis@epa.gov](mailto:Weinstock.Lewis@epa.gov)>; Thurman, James <[Thurman.James@epa.gov](mailto:Thurman.James@epa.gov)>; Shappley, Ned <[Shappley.Ned@epa.gov](mailto:Shappley.Ned@epa.gov)>; Hemby, James <[Hemby.James@epa.gov](mailto:Hemby.James@epa.gov)>  
**Subject:** Sampling and Modeling Plan - EtO - Sterigenics Willowbrook .docx

Mike,

Here is the 1-pager that Clint requested to share with Alec in IL prior to any call we might have with technical staff on the modeling and monitoring. If you are comfortable with this version, please share with Clint.


Thanks  
Chet

## Mahgoub, Gaida

---

**From:** Smith, Darcie  
**Sent:** Thursday, October 18, 2018 3:08 PM  
**To:** Holder, Chris  
**Subject:** FW: OLD - Revised MACT Actual Risk Results

Hold off on OLD for now... Thanks 😊

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Woody, Matthew  
**Sent:** Thursday, October 18, 2018 2:13 PM  
**To:** Jill Mozier <[jmozier@scainc.com](mailto:jmozier@scainc.com)>; Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Cc:** Catherine Gaertner <[cgaertner@scainc.com](mailto:cgaertner@scainc.com)>; Hollingsworth, Terri <[Hollingsworth.Terri@epa.gov](mailto:Hollingsworth.Terri@epa.gov)>; Steve Fudge <[sfudge@scainc.com](mailto:sfudge@scainc.com)>  
**Subject:** RE: OLD - Revised MACT Actual Risk Results

Hi Jill,

Hold off on modeling for both actuals and acute. You'll have new emission files coming shortly. Stay tuned...

Matt

---

**From:** Jill Mozier [<mailto:jmozier@scainc.com>]  
**Sent:** Thursday, October 18, 2018 1:14 PM  
**To:** Woody, Matthew <[Woody.Matthew@epa.gov](mailto:Woody.Matthew@epa.gov)>; Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Cc:** Catherine Gaertner <[cgaertner@scainc.com](mailto:cgaertner@scainc.com)>; Hollingsworth, Terri <[Hollingsworth.Terri@epa.gov](mailto:Hollingsworth.Terri@epa.gov)>; Steve Fudge <[sfudge@scainc.com](mailto:sfudge@scainc.com)>  
**Subject:** RE: OLD - Revised MACT Actual Risk Results

Oh, great – thanks, Matt!

Jill Mozier  
(984) 234-3968  
[jmozier@scainc.com](mailto:jmozier@scainc.com)

---

**From:** Woody, Matthew <[Woody.Matthew@epa.gov](mailto:Woody.Matthew@epa.gov)>  
**Sent:** Thursday, October 18, 2018 1:13 PM  
**To:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>; Jill Mozier <[jmozier@scainc.com](mailto:jmozier@scainc.com)>  
**Cc:** Catherine Gaertner <[cgaertner@scainc.com](mailto:cgaertner@scainc.com)>; Hollingsworth, Terri <[Hollingsworth.Terri@epa.gov](mailto:Hollingsworth.Terri@epa.gov)>; Steve Fudge <[sfudge@scainc.com](mailto:sfudge@scainc.com)>  
**Subject:** RE: OLD - Revised MACT Actual Risk Results

Hi Jill,

It sounds like I owe you some acute emissions. I'll send them shortly.

Matt

---

**From:** Smith, Darcie

**Sent:** Thursday, October 18, 2018 1:11 PM

**To:** Jill Mozier <[jmozier@scainc.com](mailto:jmozier@scainc.com)>; Woody, Matthew <[Woody.Matthew@epa.gov](mailto:Woody.Matthew@epa.gov)>


**Cc:** Catherine Gaertner <[cgaertner@scainc.com](mailto:cgaertner@scainc.com)>; Hollingsworth, Terri <[Hollingsworth.Terri@epa.gov](mailto:Hollingsworth.Terri@epa.gov)>; Steve Fudge <[sfudge@scainc.com](mailto:sfudge@scainc.com)>

**Subject:** RE: OLD - Revised MACT Actual Risk Results

Yes, same as before, but only this facility needs to be re-modeled.

Darcie Smith

U.S. EPA/OAQPS/ATAG

 919.541.2076

 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Jill Mozier [<mailto:jmozier@scainc.com>]

**Sent:** Thursday, October 18, 2018 12:47 PM

**To:** Woody, Matthew <[Woody.Matthew@epa.gov](mailto:Woody.Matthew@epa.gov)>; Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>

**Cc:** Catherine Gaertner <[cgaertner@scainc.com](mailto:cgaertner@scainc.com)>; Hollingsworth, Terri <[Hollingsworth.Terri@epa.gov](mailto:Hollingsworth.Terri@epa.gov)>; Steve Fudge <[sfudge@scainc.com](mailto:sfudge@scainc.com)>

**Subject:** RE: OLD - Revised MACT Actual Risk Results

Darcie,

Is acute going to be remodeled as well? (We modeled acute separately last time, not with a multiplier.)

Thanks,

Jill

Jill Mozier

(984) 234-3968

[jmozier@scainc.com](mailto:jmozier@scainc.com)

---

**From:** Jill Mozier

**Sent:** Thursday, October 18, 2018 9:01 AM

**To:** Woody, Matthew <[Woody.Matthew@epa.gov](mailto:Woody.Matthew@epa.gov)>; Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>

**Cc:** Catherine Gaertner <[cgaertner@scainc.com](mailto:cgaertner@scainc.com)>; Hollingsworth, Terri <[Hollingsworth.Terri@epa.gov](mailto:Hollingsworth.Terri@epa.gov)>; Steve Fudge <[sfudge@scainc.com](mailto:sfudge@scainc.com)>

**Subject:** Re: OLD - Revised MACT Actual Risk Results

Thanks, Matt. We'll model and re-summarize today.

Darcie, Catherine will also run the additional benzene summary, and Steve will iron out that cluster analysis with you.

Thanks,

Jill

---

Jill Mozier

[jmozier@scainc.com](mailto:jmozier@scainc.com)

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---

**From:** Woody, Matthew <[Woody.Matthew@epa.gov](mailto:Woody.Matthew@epa.gov)>  
**Sent:** Thursday, October 18, 2018 8:54:26 AM  
**To:** Jill Mozier; Smith, Darcie  
**Cc:** Catherine Gaertner; Hollingsworth, Terri; Steve Fudge  
**Subject:** RE: OLD - Revised MACT Actual Risk Results

Here are the new inputs. I included the entire category, but only 211637351811 changed and needs to be remodeled.

Matt

---

**From:** Jill Mozier [<mailto:jmozier@scainc.com>]  
**Sent:** Tuesday, October 16, 2018 4:16 PM  
**To:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>; Woody, Matthew <[Woody.Matthew@epa.gov](mailto:Woody.Matthew@epa.gov)>  
**Cc:** Catherine Gaertner <[cgaertner@scainc.com](mailto:cgaertner@scainc.com)>; Hollingsworth, Terri <[Hollingsworth.Terri@epa.gov](mailto:Hollingsworth.Terri@epa.gov)>; Steve Fudge <[sfudge@scainc.com](mailto:sfudge@scainc.com)>  
**Subject:** RE: OLD - Revised MACT Actual Risk Results

No problem, Darcie – you're quite welcome! We'll await the new inputs for that facility from Matt. Then we'll re-summarize and also run the max benzene post-processor program. Finally, Steve will prepare the census block/GIS-related results you two just talked about.

Thanks for the heads up,

Jill

Jill Mozier  
(984) 234-3968  
[jmozier@scainc.com](mailto:jmozier@scainc.com)

---

**From:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Sent:** Tuesday, October 16, 2018 4:09 PM  
**To:** Jill Mozier <[jmozier@scainc.com](mailto:jmozier@scainc.com)>; Woody, Matthew <[Woody.Matthew@epa.gov](mailto:Woody.Matthew@epa.gov)>  
**Cc:** Catherine Gaertner <[cgaertner@scainc.com](mailto:cgaertner@scainc.com)>; Hollingsworth, Terri <[Hollingsworth.Terri@epa.gov](mailto:Hollingsworth.Terri@epa.gov)>; Steve Fudge <[sfudge@scainc.com](mailto:sfudge@scainc.com)>  
**Subject:** RE: OLD - Revised MACT Actual Risk Results

Thanks for doing this so quickly!! Unfortunately, we need you to do it again... That same facility will be revised again and Matt will be sending new inputs to you, likely tomorrow. Good news is you're experts in the OLD category now 😊

## Ex. 5 Deliberative Process (DP)

Thanks,  
Darcie

Darcie Smith  
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📞 919.541.2076  
✉️ [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Jill Mozier [<mailto:jmozier@scainc.com>]  
**Sent:** Thursday, October 11, 2018 10:19 AM  
**To:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>; Woody, Matthew <[Woody.Matthew@epa.gov](mailto:Woody.Matthew@epa.gov)>  
**Cc:** Catherine Gaertner <[cgaertner@scainc.com](mailto:cgaertner@scainc.com)>; Hollingsworth, Terri <[Hollingsworth.Terri@epa.gov](mailto:Hollingsworth.Terri@epa.gov)>  
**Subject:** RE: OLD - Revised MACT Actual Risk Results

Darcie and Matt,

## Ex. 5 Deliberative Process (DP)

Jill Mozier  
(984) 234-3968  
[jmozier@scainc.com](mailto:jmozier@scainc.com)

---

**From:** Jill Mozier  
**Sent:** Thursday, October 11, 2018 9:55 AM  
**To:** 'Smith, Darcie' <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>; 'Woody, Matthew' <[Woody.Matthew@epa.gov](mailto:Woody.Matthew@epa.gov)>

**Cc:** Catherine Gaertner <[cgaertner@scainc.com](mailto:cgaertner@scainc.com)>; 'hollingsworth.terri@epa.gov' <[Hollingsworth.Terri@epa.gov](mailto:Hollingsworth.Terri@epa.gov)>

**Subject:** RE: OLD - Revised MACT Actual Risk Results

Darcie and Matt,

## Ex. 5 Deliberative Process (DP)

I've replaced the summary outputs on your FTP, and am in the process of replacing the facility folder, KMZ and inputs.

Jill Mozier  
(984) 234-3968  
[jmozier@scainc.com](mailto:jmozier@scainc.com)

---

**From:** Jill Mozier

**Sent:** Tuesday, October 2, 2018 4:07 PM

**To:** 'Smith, Darcie' <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>

**Cc:** Catherine Gaertner <[cgaertner@scainc.com](mailto:cgaertner@scainc.com)>; 'hollingsworth.terri@epa.gov' <[Hollingsworth.Terri@epa.gov](mailto:Hollingsworth.Terri@epa.gov)>

**Subject:** OLD - Revised MACT Actual Risk Results

Darcie,

## Ex. 5 Deliberative Process (DP)

# Ex. 5 Deliberative Process (DP)

I've replaced/updated the summaries on EPA's FTP under the OLD folder ("Actual\_plus\_Acute\_Oct-2018" subfolder), as well as the facility folder and KMZ for the re-modeled facility. I will also post the updated inputs for both Actual and Acute.

## Ex. 5 Deliberative Process (DP)

Catherine is modeling the Whole Facility revisions now.

Jill Mozier  
(984) 234-3968  
[jmozier@scainc.com](mailto:jmozier@scainc.com)

---

**From:** Jill Mozier  
**Sent:** Thursday, September 13, 2018 12:19 PM  
**To:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Cc:** Catherine Gaertner <[cgaertner@scainc.com](mailto:cgaertner@scainc.com)>; 'hollingsworth.terri@epa.gov' <[Hollingsworth.Terri@epa.gov](mailto:Hollingsworth.Terri@epa.gov)>  
**Subject:** OLD - Revised Acute Risk Results

Darcie,

## Ex. 5 Deliberative Process (DP)

I've attached the new acute impact flags summary file, as I don't currently have access to your FTP (because I'm working from home). I will post the summary plus the acute KMZs for the facilities with an acute HQ  $\geq 1.5$  to your FTP on Monday.

We are closing the office today, but, assuming I have power, I will be working from home tomorrow. So, you can reach me via e-mail or my cell (919) Ex. 5 Personal Privacy (PP)

Thanks and stay safe during the storm!  
Jill

---

**From:** Jill Mozier  
**Sent:** Wednesday, September 12, 2018 3:59 PM  
**To:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>

Cc: Catherine Gaertner <[cgaertner@scainc.com](mailto:cgaertner@scainc.com)>; 'hollingsworth.terri@epa.gov' <[Hollingsworth.Terri@epa.gov](mailto:Hollingsworth.Terri@epa.gov)>

Subject: RE: OLD - Revised MACT Actual Risk Results (chronic)

Darcie,

## Ex. 5 Deliberative Process (DP)

I'm in the processing of replacing the outputs on ATAG's FTP. Catherine is re-summarizing Acute and I will send that result soon.

Thanks,  
Jill

Jill Mozier  
(984) 234-3968  
[jmozier@scainc.com](mailto:jmozier@scainc.com)

---

**From:** Jill Mozier

**Sent:** Thursday, September 6, 2018 3:34 PM

**To:** 'Smith, Darcie' <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>

**Cc:** Catherine Gaertner <[cgaertner@scainc.com](mailto:cgaertner@scainc.com)>; 'hollingsworth.terri@epa.gov' <[Hollingsworth.Terri@epa.gov](mailto:Hollingsworth.Terri@epa.gov)>

**Subject:** OLD - Revised MACT Actual Risk Results (chronic)

Darcie,

## Ex. 5 Deliberative Process (DP)

Acute is being modeled now and I'll send you those results tomorrow. I'm uploading the (chronic) summary files to your FTP under the OLD folder and "Actual\_plus\_Acute\_Sept-2018" subfolder. I will upload the facility folders with the acute results tomorrow.

I'll also let Chris Holder know tomorrow when the facility folders are posted, so he can get the all\_polar outputs he needs for his analysis.

Jill Mozier  
(984) 234-3968  
[jmozier@scainc.com](mailto:jmozier@scainc.com)

---

**From:** Jill Mozier  
**Sent:** Thursday, April 19, 2018 4:20 PM  
**To:** 'Smith, Darcie' <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Cc:** Catherine Gaertner <[cgaertner@scainc.com](mailto:cgaertner@scainc.com)>; 'hollingsworth.terri@epa.gov' <[Hollingsworth.Terri@epa.gov](mailto:Hollingsworth.Terri@epa.gov)>  
**Subject:** OLD - Whole Facility Risk Results

Darcie,

## Ex. 5 Deliberative Process (DP)

I've attached the summary outputs, based on whole emissions – all except the multipathway\_tier2 (which is still running) and the source type histogram (completed, but I was hoping to get a few more source types spelled out).

Speaking of which, I have also (separately) attached the multipathway\_tier2 and source type histogram from the actual run – sorry for the delay.

I'm going to post all of our usual outputs to our SFTP, as a holding area. When I am granted access to your FTP, I will also upload them there. (I have requested access via the "EPA Web Application Access" portal, but have not yet been granted access.)

I'm assuming you (and SPPD) need some time to digest these outputs, but just let me know when you're ready for me to start on the draft risk report.

Thanks,  
Jill

Jill Mozier  
(919) 433-8334  
[jmozier@scainc.com](mailto:jmozier@scainc.com)

---

**From:** Jill Mozier

**Sent:** Sunday, April 15, 2018 9:19 PM

**To:** 'Smith, Darcie' <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>

**Cc:** Catherine Gaertner <[cgaertner@scainc.com](mailto:cgaertner@scainc.com)>; 'hollingsworth.terri@epa.gov' <[Hollingsworth.Terri@epa.gov](mailto:Hollingsworth.Terri@epa.gov)>

**Subject:** RE: OLD - MACT Actual plus Acute Risk Results

Darcie,

# Ex. 5 Deliberative Process (DP)

I've attached a zipped file of the summaries. I will send you the source type histogram and the multipathway\_tier2 summary tomorrow (Monday), as they are both still running.

Do you have a OneDrive to which you want me to upload facility folders, etc, or are you waiting on the ATAG FTP to be ready? Just let me know what files I can send you in the meantime.

OLD Whole should be ready in a day or two.

Thanks again for your patience,  
Jill

Jill Mozier  
(919) 433-8334  
[jmozier@scainc.com](mailto:jmozier@scainc.com)

---

**From:** Jill Mozier  
**Sent:** Thursday, April 12, 2018 5:48 PM  
**To:** 'Smith, Darcie' <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Cc:** Catherine Gaertner <[cgaertner@scainc.com](mailto:cgaertner@scainc.com)>; 'hollingsworth.terri@epa.gov' <[Hollingsworth.Terri@epa.gov](mailto:Hollingsworth.Terri@epa.gov)>  
**Subject:** OLD - MACT Actual plus Acute Risk Results

Darcie,

We modeled Actual plus Acute emissions from the Organic Liquids Distribution (OLD) source category and here are the preliminary risk results –

## Ex. 5 Deliberative Process (DP)

I've attached the summary outputs for the above. Just change the extension to "zip" after saving to your PC. I will finalize the source type histogram and submit that plus the Multipathway Tier 2 summary (which is still running) tomorrow.

I will also post all outputs to our SFTP, as a staging area, but let me know if you'd like me to e-mail any other outputs or upload all outputs to one of EPA's OneDrives, etc.

OLD Whole Facility is still running, but was temporarily interrupted for the Ethylene Production re-run.

Thanks,  
Jill

---

Jill Mozier  
Environmental Engineer

(919) 433-8334

Chapel Hill, North Carolina

[jmozier@scainc.com](mailto:jmozier@scainc.com)

[www.scainc.com](http://www.scainc.com)





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## Mahgoub, Gaida

---

**From:** Smith, Darcie  
**Sent:** Friday, October 19, 2018 9:53 AM  
**To:** Riha, Kristin  
**Subject:** FW: R% NATA Results Slides  
**Attachments:** Region 5 2014 NATA Results Slides.pptx

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
 919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Palma, Ted  
**Sent:** Thursday, October 18, 2018 4:10 PM  
**To:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Subject:** R% NATA Results Slides

Use as you would like in R5 presentation

Ted Palma  
USEPA  
OAQPS/HEID/ATAG  
MD C539-02  
RTP, NC 27711


919-541-5470 (work)  
[palma.ted@epa.gov](mailto:palma.ted@epa.gov)

## Mahgoub, Gaida

---

**From:** Smith, Darcie  
**Sent:** Tuesday, September 4, 2018 2:27 PM  
**To:** Bremer, Kristen;Palma, Ted  
**Cc:** Riha, Kristin  
**Subject:** RE: NATA one-pager for Wheeler

Thanks Kristen. I only know of the one facility in CO. I'll start with the R5 pager (thank you for sending!) and tailor it.

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Bremer, Kristen  
**Sent:** Tuesday, September 04, 2018 1:12 PM  
**To:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>; Palma, Ted <[Palma.Ted@epa.gov](mailto:Palma.Ted@epa.gov)>  
**Subject:** NATA one-pager for Wheeler  
**Importance:** High

Acting Administrator Wheeler's office is asking for a one page background memo on NATA regarding EtO with any Colorado and Montana specific information. This would include any official statements that have been made (presumably related to these two states). Would you have something we could retool? I know there were some articles about air monitoring at the Lakewood, CO, facility, but that's all I can think of at the moment.

Let me know. They've asked for materials by COB tomorrow. Thanks!



---

Kristen Bremer  
Policy Analysis & Communications  
U.S. EPA, Office of Air Quality Planning & Standards  
Email: [bremer.kristen@epa.gov](mailto:bremer.kristen@epa.gov)  
Phone: 919.541.9424  
Cell: 919.321.7652

## Mahgoub, Gaida

---

**From:** Smith, Darcie  
**Sent:** Thursday, November 1, 2018 11:02 AM  
**To:** Kelly Rimer  
**Subject:** do you want/need me there?


Darcie Smith  
U.S. EPA/OAQPS/ATAG  
 919-541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

## Mahgoub, Gaida

---

**From:** Smith, Darcie  
**Sent:** Wednesday, November 7, 2018 11:16 AM  
**To:** Kelly Rimer  
**Subject:** FW: Update on OLD RTR

Okay, so now we have more time on OLD. That's good.

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Diem, Art  
**Sent:** Wednesday, November 07, 2018 11:15 AM  
**To:** Carey, Angela <Carey.Angela@epa.gov>; Shine, Brenda <Shine.Brenda@epa.gov>; Dewees, Jason <Dewees.Jason@epa.gov>; Garwood, Gerri <Garwood.Gerri@epa.gov>; Smith, Darcie <Smith.Darcie@epa.gov>; Sorrels, Larry <Sorrels.Larry@epa.gov>; Lancey, Susan <lancey.susan@epa.gov>; Ford, Debbie <Ford.Debbie@epa.gov>; Newhouse, Rebecca <newhouse.rebecca@epa.gov>; Versace, Paul <Versace.Paul@epa.gov>; Lamson, Amy <Lamson.Amy@epa.gov>; Lo, Doris <Lo.Doris@epa.gov>; Tong, Stanley <Tong.Stanley@epa.gov>; Cox, John <Cox.John@epa.gov>; Parker, Barrett <Parker.Barrett@epa.gov>; Law, Nicole <Law.Nicole@epa.gov>; Secrest, Cary <Secrest.Cary@epa.gov>; Benner, Tim <Benner.Tim@epa.gov>  
**Subject:** Update on OLD RTR

Hi OLD Workgroup,

We had an informational briefing with Bill Wehrum last Monday. During the meeting, he requested to know and understand the refinery fenceline monitoring program better before considering fenceline monitoring as an option for OLD. Therefore, an informational briefing about fenceline monitoring will occur on November 14 (previously scheduled time for Option Selection). We just requested a new Option Selection meeting for Tuesday November 27 or Wednesday November 28.

Also, the **\*DRAFT\*** OLD risk model input files are posted on EPA's OLD NESHAP web page.

Thanks,  
Art

.....  
Art Diem, Environmental Engineer  
USEPA Office of Air Quality Planning and Standards,  
Sector Policies and Programs Division,  
Refining and Chemicals Group  
[Diem.Art@epa.gov](mailto:Diem.Art@epa.gov)  
919-541-1185

**From:** Smith, Darcie  
**Sent:** Wednesday, November 7, 2018 4:57 PM  
**To:** Strum, Madeleine  
**Subject:** RE: NATA Overview

## Ex. 5 Deliberative Process (DP)

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
[smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Strum, Madeleine  
**Sent:** Wednesday, November 07, 2018 1:32 PM  
**To:** Smith, Darcie <Smith.Darcie@epa.gov>  
**Subject:** RE: NATA Overview

Hi Darcie  
Are the yellow questions for me to answer?  
Madeleine

-----Original Appointment-----

**From:** Smith, Darcie  
**Sent:** Monday, November 5, 2018 11:14 AM  
**To:** Smith, Darcie; Kyprianou, Rose; Weiss, Steven; Leighton, Timothy; Dole, Timothy; Lowe, Kelly; Shelat, Shalu; Rimer, Kelly; Strum, Madeleine; Morris, Mark; Palma, Ted; Bailey, Jessica  
**Cc:** Metzger, Michael; Anderson, Neil; McMahon, Tim; Loudon, Ruthanne; Kent, Ray; Arrington, Linda; Bartow, Susan; Fehir, Richard; Gayoso, Jose  
**Subject:** NATA Overview  
**When:** Monday, November 19, 2018 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).  
**Where:**

*If this time doesn't work, an alternative time is Thursday Nov 15 at noon. Just let me know.*

Purpose: to walk through NATA and the Map App, and to answer the highlighted questions below. Also, to hear about the re-evaluation process for ethylene oxide.

Logistics – to be determined.

## Ex. 5 Deliberative Process (DP)

# **Ex. 5 Deliberative Process (DP)**

## Mahgoub, Gaida

---

**From:** Smith, Darcie  
**Sent:** Friday, November 9, 2018 1:37 PM  
**To:** Rimer, Kelly  
**Subject:** RE: Can you call me before 1 pm your time ?

No, but I can call you now, if you still need me.

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
smith.darcie@epa.gov

-----Original Message-----

**From:** Rimer, Kelly  
**Sent:** Friday, November 09, 2018 11:56 AM  
**To:** Smith, Darcie <Smith.Darcie@epa.gov>  
**Subject:** Can you call me before 1 pm your time ?

919: Ex. 6 Personal Privacy (PP)

**Mahgoub, Gaida**

---

**From:** Smith, Darcie  
**Sent:** Thursday, November 8, 2018 4:55 PM  
**To:** Davis, Alison  
**Subject:** RE: Ethylene oxide emissions in Lake County

My thoughts. I can help track down more loose ends, if there are any left, tomorrow. See you then!

## **Ex. 5 Deliberative Process (DP)**

# **Ex. 5 Deliberative Process (DP)**

## **Mahgoub, Gaida**

---

**From:** Davis, Alison  
**Sent:** Friday, November 9, 2018 5:45 PM  
**To:** Koerber, Mike;Weinstock, Lewis;Shappley, Ned;Rimer, Kelly;Bremer, Kristen;Smith, Darcie  
**Cc:** Wayland, Richard  
**Subject:** Region 5 monitoring starting Tuesday

Hi all – Katie Siegel called to tell me R5 will be putting the first two cans out on Tuesday morning. They are drafting up a small index-sized card that their employees can hand to anyone who asks questions and will send me that for review this weekend. We'll need to get the info on monitoring posted as soon as we can on Tuesday.

Mike, will you flag for Clint?

Thanks  
-Alison

**Mahgoub, Gaida**

---

**From:** Strum, Madeleine  
**Sent:** Tuesday, February 12, 2019 11:37 PM  
**To:** Smith, Darcie  
**Subject:** For ETO briefing

Hi

# Ex. 5 Deliberative Process (DP)

Madeleine Strum|U.S. Environmental Protection Agency|109 TW Alexander Drive, RTP, NC 27711  
Office of Air Quality Planning and Standards|Air Quality Assessment Division|Emission Inventory and Analysis Group|919 541 2383

## **Mahgoub, Gaida**

---

**Subject:** NATA outreach

**Location:** RLO

**Start:** Tue 6/26/2018 12:00 PM

**End:** Tue 6/26/2018 12:30 PM

**Show Time As:** Tentative

**Recurrence:** (none)

**Meeting Status:** Tentatively accepted

**Organizer:** Riha, Kristin

**Required Attendees** Langdon, Robin; Smith, Darcie; Truesdell, Raymond

**Mahgoub, Gaida**

---


**From:** Smith, Darcie  
**Sent:** Monday, February 11, 2019 6:25 PM  
**To:** Diem, Art  
**Subject:** RE: whole facility risk?

Hi Art –

Let's talk some more.

**Ex. 5 Deliberative Process (DP)**

Thanks,  
Darcie

Darcie Smith  
U.S. EPA/OAQPS/ ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Diem, Art  
**Sent:** Friday, February 08, 2019 10:59 AM  
**To:** Smith, Darcie <Smith.Darcie@epa.gov>  
**Subject:** whole facility risk?

Hi Darcie,

**Ex. 5 Deliberative Process (DP)**

.....  
Art Diem, Environmental Engineer  
USEPA Office of Air Quality Planning and Standards,  
Sector Policies and Programs Division, Refining and Chemicals Group  
[Diem.Art@epa.gov](mailto:Diem.Art@epa.gov)  
919-541-1185

**Mahgoub, Gaida**

---

**From:** Shappley, Ned  
**Sent:** Monday, June 25, 2018 2:32 PM  
**To:** Langdon, Robin  
**Cc:** Smith, Darcie  
**Subject:** RE: Updated Ethylene Oxide Monitoring Write Up

Robin,

Attached are my comments. I am a little concerned with how we discuss the development of new ambient sampling techniques. I want to make sure that we are not overselling what we can do.

## Ex. 5 Deliberative Process (DP)

Thanks,  
Ned

---

**From:** Langdon, Robin  
**Sent:** Monday, 25 June, 2018 13:52  
**To:** Shappley, Ned <Shappley.Ned@epa.gov>  
**Cc:** Smith, Darcie <Smith.Darcie@epa.gov>  
**Subject:** Updated Ethylene Oxide Monitoring Write Up

Hi Ned,

I slightly rearranged the write up you provided on Friday. Per my voicemail, can you please read the attached version and confirm that it remains accurate?

We'd like to send this to Chet and Mike Koerber as quickly as we can.

Than you again,  
Robin

Robin Langdon  
USEPA  
Office of Air Quality Planning & Standards  
Durham, NC 27711  
919.541.5695  
[langdon.robin@epa.gov](mailto:langdon.robin@epa.gov)

**Mahgoub, Gaida**

---

**From:** Houyoux, Marc  
**Sent:** Monday, June 25, 2018 5:26 PM  
**To:** Smith, Darcie;Langdon, Robin  
**Cc:** Strum, Madeleine  
**Subject:** RE: scatter plot/historgram of EtO facilities/emissions

**Importance:** High

Darcie and Robin-

The data that you requested is attached. Please take a look at the Readme tab for some important notes.

Other data fields are available if needed.

I have added a few fields that you may find helpful.

## Ex. 5 Deliberative Process (DP)

Marc

DELIBERATIVE FOR INTERNAL USE. DRAFT.

-----  
Marc Houyoux  
Group Leader  
Emissions Inventory and Analysis Group  
EPA/OAQPS/AQAD  
919-541-3649

-----  
**From:** Smith, Darcie  
**Sent:** Monday, June 25, 2018 12:46 PM  
**To:** Houyoux, Marc <Houyoux.Marc@epa.gov>; Langdon, Robin <Langdon.Robin@epa.gov>  
**Subject:** FW: scatter plot/histogram of EtO facilities/emissions


Hi Marc –

Robin is going to call you to provide some additional context for this request.

# Ex. 5 Deliberative Process (DP)

This is needed as soon as possible, in order to provide additional information on the topic.

Thanks,  
Darcie

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Strum, Madeleine  
**Sent:** Tuesday, June 19, 2018 8:32 PM  
**To:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Subject:** RE: scatter plot/histogram of EtO facilities/emissions

Darcie,

## Ex. 5 Deliberative Process (DP)

Madeleine


---

**From:** Smith, Darcie  
**Sent:** Tuesday, June 19, 2018 6:09 PM  
**To:** Strum, Madeleine <[Strum.Madeleine@epa.gov](mailto:Strum.Madeleine@epa.gov)>  
**Subject:** RE: scatter plot/histogram of EtO facilities/emissions

Hi Madeleine –

### Ex. 5 Deliberative Process (DP)

Thanks!

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

**From:** Strum, Madeleine  
**Sent:** Tuesday, June 12, 2018 7:39 PM  
**To:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Subject:** RE: scatter plot/histogram of EtO facilities/emissions

## **Ex. 5 Deliberative Process (DP)**

**From:** Strum, Madeleine  
**Sent:** Tuesday, June 12, 2018 7:16 PM  
**To:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>  
**Subject:** RE: scatter plot/histogram of EtO facilities/emissions

## **Ex. 5 Deliberative Process (DP)**

# **Ex. 5 Deliberative Process (DP)**

## Mahgoub, Gaida

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**From:** Smith, Darcie  
**Sent:** Wednesday, June 27, 2018 8:58 AM  
**To:** Palma, Ted (Palma.Ted@epa.gov); Morris, Mark; Woody, Matthew; Truesdell, Raymond; Strum, Madeleine; Eyth, Alison; Phillips, Sharon; Thurman, James; Cook, Rich  
**Subject:** FW: NATA Results: Materials in prep for tomorrow's briefing with Bill W  
**Attachments:** 2014 NATA Results Briefing 06\_27\_18.pptx

Here are the slides for this morning's NATA mtg. It will largely focus on ethylene oxide.

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
📞 919.541.2076  
✉️ [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** South, Peter  
**Sent:** Tuesday, June 26, 2018 6:21 PM  
**To:** Harnett, Bill <Harnett.Bill@epa.gov>; Koerber, Mike <Koerber.Mike@epa.gov>; McKinney, Voronina <mckinney.voronina@epa.gov>; OAQPS WOPS <OAQPS\_WOPS@epa.gov>; OAR Briefings <OAR\_Briefings@epa.gov>  
**Cc:** Sasser, Erika <Sasser.Erika@epa.gov>; Langdon, Robin <Langdon.Robin@epa.gov>; Houyoux, Marc <Houyoux.Marc@epa.gov>; Jones, Rhea <Jones.Rhea@epa.gov>; Mozingo, Kristal <Mozingo.Kristal@epa.gov>; Wayland, Richard <Wayland.Richard@epa.gov>; Bremer, Kristen <Bremer.Kristen@epa.gov>; Tsirigotis, Peter <Tsirigotis.Peter@epa.gov>; Koerber, Mike <Koerber.Mike@epa.gov>; Harnett, Bill <Harnett.Bill@epa.gov>; Riha, Kristin <Riha.Kristin@epa.gov>; Smith, Darcie <Smith.Darcie@epa.gov>  
**Subject:** NATA Results: Materials in prep for tomorrow's briefing with Bill W

I have attached the briefing materials in prep for tomorrow's NATA meeting with Bill.

Please call me or Mike with any questions relating to this information.

Thank you.

Pete South  
OAR/OAQPS/IO  
U.S. EPA  
office: 919 541-5359  
cell: 919 599-7213

Organizer ☐ Wehrum, Bill

Subject NATA Results

Location C401AHQ Room WJC-N 5400 + Video with RTP Room C401A + 919- (no code)

Start time Wed 6/27/2018  ☐ All day event

End time Wed 6/27/2018

**TO:** Wehrum, Bill; Harlow, David; Woods, Clint; Tsirigotis, Peter; Koerber, Mike; Wayland, Richard; Darcie; Strum, Madeleine; Farkas, Caroline; Shelow, David; Palma, Ted; Eyth, Alison; Morris, Mark; Jenny; Cook, Rich; Grundler, Chris; Dunham, Sarah; Edwards, Jonathan;

**Mahgoub, Gaida**

---

**From:** Morris, Mark  
**Sent:** Thursday, June 28, 2018 9:51 AM  
**To:** Smith, Darcie;Palma, Ted  
**Cc:** Truesdell, Raymond  
**Subject:** RE: can you pls help my understanding of aggregating from blocks to tracts in NATA?

My understanding (I'm ignoring the monitor locations as receptors here):

## Ex. 5 Deliberative Process (DP)

Mark Morris  
USEPA  
Mailcode C539-02  
109 TW Alexander Drive  
RTP, NC 27711  
(919) 541-5416  
[morris.mark@epa.gov](mailto:morris.mark@epa.gov)

---

**From:** Smith, Darcie  
**Sent:** Wednesday, June 27, 2018 6:03 PM  
**To:** Morris, Mark <Morris.Mark@epa.gov>; Palma, Ted <Palma.Ted@epa.gov>  
**Cc:** Truesdell, Raymond <truesdell.raymond@epa.gov>  
**Subject:** can you pls help my understanding of aggregating from blocks to tracts in NATA?

Hi Mark and Ted -

I'm reading the methods pages and just want to confirm my understanding of the process steps for modeling and

# Ex. 5 Deliberative Process (DP)

Thanks,  
Darcie

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
📞 919.541.2076  
✉️ [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)


## Mahgoub, Gaida

---

**From:** Smith, Darcie  
**Sent:** Wednesday, June 27, 2018 1:36 PM  
**To:** Stone, William; Strum, Madeleine  
**Subject:** RE: OAR AA Briefing Today RE: EtO facilities in 2014 NATA

Thanks Will.

An update for you – we did not get into any facility specifics this morning.

Darcie Smith  
U.S. EPA/OAQPS/ ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

---

**From:** Stone, William  
**Sent:** Wednesday, June 27, 2018 1:09 PM  
**To:** Smith, Darcie <[Smith.Darcie@epa.gov](mailto:Smith.Darcie@epa.gov)>; Strum, Madeleine <[Strum.Madeleine@epa.gov](mailto:Strum.Madeleine@epa.gov)>  
**Subject:** FW: OAR AA Briefing Today RE: EtO facilities in 2014 NATA

FYI.

---

**From:** Johnson, Karen T.  
**Sent:** Wednesday, June 27, 2018 11:46 AM  
**To:** Doolan, Stephanie <[Doolan.Stephanie@epa.gov](mailto:Doolan.Stephanie@epa.gov)>; Jay, Michael <[Jay.Michael@epa.gov](mailto:Jay.Michael@epa.gov)>; Werner, Leslye <[Werner.Leslye@epa.gov](mailto:Werner.Leslye@epa.gov)>; Algae-Eakin, Amy <[Algae-Eakin.Amy@epa.gov](mailto:Algae-Eakin.Amy@epa.gov)>; Stone, William <[stone.william@epa.gov](mailto:stone.william@epa.gov)>  
**Subject:** RE: OAR AA Briefing Today RE: EtO facilities in 2014 NATA

Hi Friends

FYI - our inspector Sean Bergin has completed Air and TRI inspections of the Midwest Sterilization Co facility in Jackson, MO. Sean found the facility to be complying with their permit and not have any emission exceedances. I am reviewing the report now.

-Karen

---

**From:** Doolan, Stephanie  
**Sent:** Wednesday, June 27, 2018 11:38 AM  
**To:** Jay, Michael <[Jay.Michael@epa.gov](mailto:Jay.Michael@epa.gov)>; Werner, Leslye <[Werner.Leslye@epa.gov](mailto:Werner.Leslye@epa.gov)>; Algae-Eakin, Amy <[Algae-Eakin.Amy@epa.gov](mailto:Algae-Eakin.Amy@epa.gov)>  
**Cc:** Stone, William <[stone.william@epa.gov](mailto:stone.william@epa.gov)>; Johnson, Karen T. <[Johnson.Karent@epa.gov](mailto:Johnson.Karent@epa.gov)>  
**Subject:** OAR AA Briefing Today RE: EtO facilities in 2014 NATA

All,

Will was contacted by OAQPS late yesterday and told that the AA will be briefed today about the 2014 NATA risk modeling results, and, particularly, about risks from ethylene oxide facilities. As I emailed you about earlier (see below), Region 7 has the highest block risk in the nation for the BCP

facility in Verona, MO, but the tract risk is much lower. For Midwest Sterilization Corp in Cape Girardeau, the tract risk is the highest in R7 also due to EtO emissions. *The risk from EtO is higher in the 2014 NATA release because the IRIS toxicity value was re-evaluated and lowered by 40%.*

Please let me know if you have any questions. Will and I will keep you posted about when to expect the public release of the 2014 NATA and any briefing materials that are prepared to support that release.

*Thank you!*

*Stephanie B. Doolan  
Air & Waste Management Division  
Air Planning and Development Branch  
(913) 551-7719  
[Doolan.stephanie@epa.gov](mailto:Doolan.stephanie@epa.gov)*

---

**From:** Doolan, Stephanie  
**Sent:** Tuesday, June 13, 2017 3:06 PM  
**To:** Jay, Michael <[jay.michael@epa.gov](mailto:jay.michael@epa.gov)>; Werner, Leslye <[Werner.Leslye@epa.gov](mailto:Werner.Leslye@epa.gov)>; Kemp, Lachala <[Kemp.Lachala@epa.gov](mailto:Kemp.Lachala@epa.gov)>  
**Cc:** Stone, William <[stone.william@epa.gov](mailto:stone.william@epa.gov)>; Johnson, Karen T. <[Johnson.Karent@epa.gov](mailto:Johnson.Karent@epa.gov)>  
**Subject:** RE: EtO facilities in MO / 2014 NATA Update

Will and I have been looking at the tract level risks and below is the information he put together for me. The Cape Girardeau Co. facility has the highest risk of the EtO facilities and of all facilities in the four-state region. As you can see from the previous email which contained the facility-specific risk, the tract level risk is much less, but still significant. We have discussed the facility with MDNR and Karen Johnson has put it on the 2018 inspection list. Will and I have joined a NATA sub-group to discuss and share information on EtO facilities.

Please let us know if you have questions or comments. Unless there is a "game-changer" that I don't know about now, these facilities will be the highest risk facilities in the public release of the 2014 NATA. With the help of the subgroup, we'll be ready with an internal briefing to prepare us for the public release and any questions we may receive. Look forward (or not!) to a briefing closer to the release date.

\Stephanie, I downloaded the 4 files. I started with cancer risk by poll. We have a couple that stand out. Here's all the tracts above 60 per million.

State	EPA Region	County	FIPS	Tract	Population	Total Cancer Risk (per million)
MO	EPA Region 7	Cape Girardeau	29031	29031880400	6908	1
IA	EPA Region 7	Linn	19113	19113002200	1832	
MO	EPA Region 7	Lawrence	29109	29109470300	5445	
IA	EPA Region 7	Linn	19113	19113002600	2416	
MO	EPA Region 7	Cape Girardeau	29031	29031880500	9040	

MO	EPA Region 7	Cape Girardeau	29031	29031880200	3822	
MO	EPA Region 7	Cape Girardeau	29031	29031000000	75674	
MO	EPA Region 7	Cape Girardeau	29031	29031880300	4387	

It looks like Ethylene oxide is biggest contributor here.

ETHYLENE OXIDE
164.920
54.726
51.115
43.730
37.618
35.337
31.478
32.344

**From:** Doolan, Stephanie

**Sent:** Tuesday, April 11, 2017 2:10 PM

**To:** Algae-Eakin, Amy <[algae-eakin.amy@epa.gov](mailto:algae-eakin.amy@epa.gov)>; Jay, Michael <[jay.michael@epa.gov](mailto:jay.michael@epa.gov)>

**Cc:** Stone, William <[stone.william@epa.gov](mailto:stone.william@epa.gov)>; Johnson, Karen T. <[Johnson.Karent@epa.gov](mailto:Johnson.Karent@epa.gov)>

**Subject:** EtO facilities in MO / 2014 NATA Update

EIS facility_id	facility_name	FIPS	State or Tribe	To
7281511	BCP INGREDIENTS-VERONA PLANT	29109	Missouri	
7990911	BASF Corporation	34041	New Jersey	
7258511	WILLIAM BEAUMONT HOSPITAL	26125	Michigan	
8378211	MONTEFIORE MEDICAL CTR-111 E 210TH ST	36005	New York	
2686511	C R Bard	13217	Georgia	
4953611	AIR PRODUCTS PERFORMANCE MFG INC	55105	Wisconsin	
2534011	Kendall Healthcare Products	13245	Georgia	
14386711	BAKERSFIELD MEMORIAL HOSPITAL	06029	California	
14657611	B BRAUN MED INC/ALLENTOWN	42077	Pennsylvania	
7351811	Monument Chemical Kentucky LLC	21163	Kentucky	
7451011	BCP Ingredients Inc	22047	Louisiana	
7703311	Midwest Sterilization Corp-Jackson	29031	Missouri	

Just an FYI. There are two facilities in Missouri that are showing greater than 100 in one mil risk for ethylene oxide. Above is an excerpt from an xls file from OAQPS of all EtO facilities. Keep in mind this is facility risk at this point. In about another month, we'll have the modeled data in the app by census tract, which could change the picture. This is something new this year for the 2014 NATA b/c EPA lowered the IRIS toxicity value by a factor of 50. MDNR has been made aware and they say that the emissions are correct. Karen put the Midwest Sterilization Corp facility on the target list. My understanding is that these facilities are within their permitted limits as minor sources. When we see how they model at the census tract level, I'll report back. I was just surprised that we had the highest risk EtO facility in the nation.

*Thank you!*

*Stephanie B. Doolan  
Air & Waste Management Division  
Air Planning and Development Branch  
(913) 551-7719  
[Doolan.stephanie@epa.gov](mailto:Doolan.stephanie@epa.gov)*

**From:** Smith, Darcie  
**Sent:** Friday, July 13, 2018 1:26 PM  
**To:** Caparoso, Jennifer;Witt, Jon  
**Cc:** Strum, Madeleine;Palma, Ted (Palma.Ted@epa.gov)  
**Subject:** fyi - EtO summary table

Given the information in the spreadsheet, I summed everything up to show the potential regulatory options. Here's what it looks like, fyi. Thanks for keeping that sheet updated – it came in handy!

# Ex. 5 Deliberative Process (DP)



Darcie Smith  
U.S. EPA/OAQPS/ATAG  
📞 919.541.2076  
✉️ [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

## Mahgoub, Gaida

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**From:** Smith, Darcie  
**Sent:** Monday, August 20, 2018 5:49 PM  
**To:** Palma, Ted (Palma.Ted@epa.gov)  
**Subject:** block v tract

Tract can be higher than block when the tract is the TOTAL cancer risk in the tract and the block is ONLY EtO.

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
 919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

## Mahgoub, Gaida

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**From:** Smith, Darcie  
**Sent:** Wednesday, August 22, 2018 9:03 AM  
**To:** Phillips, Sharon;Thurman, James;Eyth, Alison;Strum, Madeleine;Palma, Ted  
(Palma.Ted@epa.gov);Woody, Matthew;Vukovich, Jeffrey;Morris, Mark;Cook, Rich;Chow, Alice;Myers,  
Jeff D - DNR  
**Subject:** another NATA update

Hey –

Today's the day! NATA should be live at 2 pm today (or whenever the files are finished uploading).

The community webinar has been moved from tomorrow to next Tuesday. I'll send details when I get them.

Thanks,  
Darcie

Darcie Smith  
U.S. EPA/OAQPS/ATAG  
919.541.2076  
 [smith.darcie@epa.gov](mailto:smith.darcie@epa.gov)

**From:** DeLuca, Isabel  
**To:** Wehrum, Bill; Woods, Clint  
**Cc:** Millett, John  
**Subject:** NATA is up  
**Date:** Wednesday, August 22, 2018 11:20:30 AM

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Hi all,

Just a heads up that NATA is now posted:

<https://wcms.epa.gov/national-air-toxics-assessment/2014-national-air-toxics-assessment>

<https://wcms.epa.gov/national-air-toxics-assessment/2014-nata-fact-sheet>

<https://wcms.epa.gov/hazardous-air-pollutants-ethylene-oxide>

**Isabel DeLuca**

Office of Air and Radiation, US EPA

(202) 343-9247

**From:** Rakosnik, Delaney on behalf of Wehrum, Bill  
**To:** Koerber, Mike; Wayland, Richard; Sasser, Erika; Weinstock, Lewis; Murphy, Deirdre; Vasu, Amy; Davis, Alison; Tsirigotis, Peter; Rimer, Kelly  
**Subject:** Prep session for R5 call  
**Attachments:** Following up on my voicemail .msg

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TO: Bill Wehrum, Mike Koerber, Richard Wayland, Erika Sasser, Lewis Weinstock, Deirdre Murphy, Amy Vasu, Alison Davis, Peter Tsirigotis, Kelly Rimer

Message

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**From:** Davis, Alison [Davis.Alison@epa.gov]  
**Sent:** 11/9/2018 2:39:59 PM  
**To:** Rakosnik, Delaney [rakosnik.delaney@epa.gov]  
**Subject:** Following up on my voicemail

Hi Delaney,

Here is the list of names for the OAQPS discussion with Bill in advance of the 4 p.m. call with R5 today. Please call if you have any questions.

Mike Koerber  
Richard Wayland  
Erika Sasser  
Lewis Weinstock  
Deirdre Murphy  
Amy Vasu  
Alison Davis

Please cc: Peter T. and Kelly Rimer (she is out)

Thanks so much!

-Alison

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Alison Davis  
Acting Director  
Policy Analysis & Communications Staff  
US EPA, Office of Air Quality Planning & Standards  
Research Triangle Park, NC 27711  
Desk: 919-541-7587  
Mobile: 919-624-0872

**From:** Woods, Clint  
**To:** Koerber, Mike; Lewis, Josh; Tsirigotis, Peter  
**Cc:** Davis, Alison; Sasser, Erika; Wayland, Richard; Cozzie, David  
**Subject:** RE: Draft talking points  
**Date:** Thursday, July 26, 2018 9:24:37 AM

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Mike,

These look great, and I think that approach makes sense. Thanks!

Clint Woods  
Deputy Assistant Administrator  
Office of Air and Radiation, U.S. EPA  
202.564.6562

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**From:** Koerber, Mike  
**Sent:** Thursday, July 26, 2018 8:04 AM  
**To:** Woods, Clint <woods.clint@epa.gov>; Lewis, Josh <Lewis.Josh@epa.gov>; Tsirigotis, Peter <Tsirigotis.Peter@epa.gov>  
**Cc:** Davis, Alison <Davis.Alison@epa.gov>; Sasser, Erika <Sasser.Erika@epa.gov>; Wayland, Richard <Wayland.Richard@epa.gov>; Cozzie, David <Cozzie.David@epa.gov>  
**Subject:** Draft talking points

Clint: Here are draft talking points to use for today's call with the RAs. Let me know what you think. My understanding is that Bill intends to kick-off the call and then hand it to OAQPS. Thanks.

Mike

**From:** [Witt, Jon](#)  
**To:** [Koerber, Mike](#)  
**Subject:** RE: voicemail  
**Date:** Thursday, June 6, 2019 9:48:42 AM  
**Attachments:** [20190607 EtO New.docx](#)

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Mike,

I incorporated your edits in the attached file. I made some changes to the project timeline section that should hopefully be more in step with what Bill indicated during the public meeting, as well as what it will take to meet the deadline he mentioned (i.e. working with OMB and SBA).

Let me know if Peter has anything he'd like to add on the (d)(6) discussion ahead of the briefing. After that, we can send it up through our IO.

Thanks,  
Jonathan

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**From:** Witt, Jon  
**Sent:** Thursday, June 06, 2019 11:50 AM  
**To:** Koerber, Mike <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)>  
**Subject:** RE: voicemail

Thanks, Mike. I'll incorporate these comments in the briefing materials.  
Jonathan

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**From:** Koerber, Mike  
**Sent:** Thursday, June 06, 2019 10:46 AM  
**To:** Witt, Jon <[Witt.Jon@epa.gov](mailto:Witt.Jon@epa.gov)>  
**Subject:** RE: voicemail

Thanks, Jonathon. A few comments:

## Ex. 5 Deliberative Process (DP)

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**From:** Witt, Jon  
**Sent:** Thursday, June 06, 2019 8:49 AM  
**To:** Koerber, Mike <[Koerber.Mike@epa.gov](mailto:Koerber.Mike@epa.gov)>  
**Subject:** RE: voicemail

Sounds good. The latest clean version of the briefing is attached. Steve still needs to review it, but HEID and OGC have already given their input on the (d)(6) discussion.

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**From:** Koerber, Mike  
**Sent:** Wednesday, June 05, 2019 5:45 PM  
**To:** Witt, Jon <[Witt.Jon@epa.gov](mailto:Witt.Jon@epa.gov)>  
**Subject:** voicemail

Yes, Peter would like to see that part of the briefing in advance. There are other related conversations already underway with OAR, so we need to make sure that this part of the briefing is consistent.

**Commercial Ethylene Oxide (EtO) Sterilizers  
Technology Review**  
Follow-Up Briefing with Bill Wehrum

**PURPOSE:** Follow-up on 5/14 discussion regarding key items related to Commercial Sterilizers, including the interim final rule and regulatory framework.

**INTERIM FINAL RULE**

- Emissions sources currently covered by the rule are provided in the table below:

Source size (EtO usage)	Sterilization chamber vent	Aeration room vent	Chamber exhaust vent	Fugitive emissions
≥10 TPY	99% emission reduction	1 ppm maximum outlet concentration or 99% emission reduction	No control. <sup>1</sup>	No control.
≥1 TPY and <10 TPY	99% emission reduction	No control.	No control. <sup>2</sup>	No control.
<1 TPY	No control.	No control.	No control.	No control.

- Previously, we discussed the following work practice standards that could be included in an interim final rule and implemented within 30 to 60 days:
  - Regular leak checks of EtO drums and sterilization chambers.
  - Maximum EtO concentration in sterilization chamber before opening.
  - Require interlock system for sterilization chambers, which would ensure gas removal before they could be opened.
- Upon further review, additional items can potentially be included in the interim final rule:
  - Chamber exhaust vent (i.e. back vent) control: Ideally, we would have a short compliance timeline (six to nine months), with opportunities for operators to petition EPA for more time due to technical or safety concerns. We can incorporate previously mentioned work practices (maximum chamber concentrations, interlock systems) to ensure safe control. Ideally, facilities where controls were previously in place would be able to re-introduce controls quickly.
  - For an average facility using 10 TPY EtO or more, controlling back vent emissions would result in an estimated 57% reduction in emissions. For a facility using 1 TPY EtO or more, this results in an estimated 31% reduction. To illustrate potential risk reductions, two facilities (Sterigenics Willowbrook and Midwest Sterilization in Missouri) were modeled before and after the addition of back vent controls. For both facilities, the maximum risk and incidence drop was close to 50%.
  - Add clarifying language that single item sterilizers are subject to the rule. This would achieve additional emissions reductions from several facilities.
  - Will need to be mindful of potential impacts on small businesses. 29% of known commercial sterilizers (34 out of 121) are small businesses.
  - In order to implement the interim final rule, we will need an emergency ICR, which will require OMB approval.
- Additional strategies for reducing emissions in the interim final rule include:

**Commented [WJ1]:** Added here since this deals with implementation, as opposed to data gathering

<sup>1</sup> Prior to December 9, 1997, required manifold to a control device controlling emissions from another vent type or 99 percent emission reduction.

<sup>2</sup> Prior to December 9, 1997, required maximum chamber concentration limit of 5,300 ppmv prior to activation of the chamber exhaust.

- In the proposed rule, it is likely that we will have a number of requirements for operators. One option is to have operators choose a number of those options to comply with as part of the interim final rule and to comply with the other requirements once the proposed rule is finalized. Would allow for a petition process for relief if operators are able to demonstrate an inability to comply with requirements. The specifics of that demonstration would be laid out in the rule.
- In lieu of controls for each emission source, allow operators to demonstrate that facility-wide average reductions are equivalent to or better than what we require. If operating under (f)(2), we can use a risk-based facility value, but this would not be possible under (d)(6).
- For facilities that use less than 1 TPY EtO, add language similar to general duty clause, though these are difficult to enforce.
- In addition, we explored the following options but uncovered certain issues with each:
  - Allowing for operators to comply with a legally and practically enforceable permit in lieu of rule requirements. This has been done under NSPS, which has more flexibility. States would also have to issue these permits quickly.
  - Delay compliance with requirements on the condition that more stringent requirements are followed in the future, similar to what was done under the Coke Ovens NESHAP. However, this strategy was explicitly provided for in CAA section 112(i)(8). In addition, this option would not achieve immediate emission reductions.

#### REGULATORY FRAMEWORK

The table below lists advantages and disadvantages of revising the NESHAP under various CAA authorities:

CAA Section 112 Authority	Advantages	Disadvantages
(d)(6)	<ul style="list-style-type: none"> <li>● Would satisfy our obligation to complete our overdue (d)(6) technology review.</li> <li>● As there is no established metric for evaluating risk under (d)(6), EPA may have discretion to conduct a more limited risk review, as warranted.</li> <li>● Risk information could be used to inform the technology review, instead of being used to make a determination regarding the acceptability of the public health risks.</li> </ul>	<ul style="list-style-type: none"> <li>● Using (d)(6) to address previously unregulated emission points (e.g. fugitive emissions) would risk expanding the scope of our statutorily required (d)(6) reviews.</li> <li>● (d)(6) does not reference the benzene NESHAP backstop, which established 100-in-a-million risk as acceptable.</li> <li>● Higher legal risk if approach would differ from prior risk analyses done to support RTRs.</li> <li>● Risk analysis approach could underestimate population-level risk metrics (e.g., number of people above 1-in-1 million risk) and may exclude some facilities that could be high risk.</li> </ul>
(f)(2)	<ul style="list-style-type: none"> <li>● References the benzene NESHAP</li> <li>● In the 2006 RTR, we said that we may re-visit (f)(2) if the IRIS value for EtO changed.</li> </ul>	<ul style="list-style-type: none"> <li>● Do not have information for a large portion of the source category (85 out of 121 facilities), which will be</li> </ul>

	<ul style="list-style-type: none"> <li>• Would provide a more comprehensive evaluation of whether proposed control strategies would appropriately mitigate risk for the source category if using model plant approach.</li> <li>• Action focused on residual risk would be consistent with use of interim final rule.</li> </ul>	<p>impact analysis if using model plants.<sup>3</sup></p> <ul style="list-style-type: none"> <li>• Incorporating model plants could add uncertainty to the risk analysis if we chose to use them.</li> <li>• Any high risk resulting from model plants use may alarm the public, but we can distinguish the results that relied on the model plants if we chose to use them.</li> </ul>
(d)(2) and (d)(3)	<ul style="list-style-type: none"> <li>• Could use this authority for the interim final rule.</li> <li>• Would help emphasize that the interim final rule is not intended to satisfy either our (d)(6) or (f)(2) obligations.</li> <li>• Case law establishes our authority to revise rules under the same authority used to initially promulgate them.</li> <li>• Additional requirements would be beyond-the-floor standards and thus we could consider cost in deciding what controls to adopt.</li> </ul>	<ul style="list-style-type: none"> <li>• Would specify that we are not re-opening the MACT floor.</li> <li>• Would have to explain why we are reopening the technology-based standard because of increased risk.</li> <li>• Would not explicitly address our re-assessment of risk, except in the "good cause" finding to justify proceeding without notice and comment.</li> </ul>

#### OTHER ITEMS

- Potential data gathering for the final rule
  - To improve the quality of the NESHAP review, we need more information on facilities using less than 1 tpy of EtO and more information for all facilities regarding the feasibility and cost of controlling emissions.
  - Should we send 114 requests to nine, or fewer entities, to obtain currently available information on fugitive emissions control or not?
  - Other options include obtaining OMB approval for an emergency ICR and sending 114 requests to nine, or fewer EtO suppliers to obtain more information on facilities that use less than 1 TPY EtO.
- Project timeline
  - Option 1: Release interim final rule in July, which will require an expedited OMB review. Send proposed rule package to OMB in August. The proposal will require discussion with SBA, as regular procedure would more than likely require a small business panel, which would add substantial time to complete the project.

**Commented [WJ2]:** Unclear if Bill committed during the public meeting to both IFR and proposed rule in July or just committed to doing some sort of action. Releasing just the IFR would be much more manageable.

<sup>3</sup> We have minimal data for facilities that use less than 1 TPY EtO and the quantity of emissions coming from different sources. For example, we may have the total stack emissions for a facility from the Toxics Release Inventory (TRI), but we would not know how much is coming from the sterilization chamber, aeration room or chamber exhaust.

- Option 2: Send the interim final rule package to OMB in July and the proposed rule package in August. The interim final and proposed rule would be in separate FR notices.
- Option 3: If interim final rule is deemed insufficient Send only the proposed rule package to OMB in August release proposed rule in July, which will require an expedited OMB review and discussion with SBA.
- Scope of risk analysis
  - Option 1: Model only a subset of facilities. Identify facilities that we have sufficient information (i.e., model all facilities that can be modeled without creating a “model plant”). Focus on facilities for which we have greater certainty.
  - Option 2: Model all facilities (using model plants where we don’t have plant specific information).

**Commented [WJ3]:** These are the two options we had before the public meeting. We wanted to present an option in case Bill felt the IFR was no longer worth doing (option 3)